Exhibit 10

Claim 1 of the 'Jang 021 Patent	Claim 23 of the Jang '021 Patent
1. A stent in a non-expanded state, comprising: a first expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the first expansion strut pair that couples the first and second expansion struts at a distal end of the first expansion strut pair, a plurality of the first expansion strut pair forming a first expansion column; a second expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the second expansion strut pair that couples the first and second expansion struts of the second expansion strut pair at a proximal end of the second expansion strut pair, a plurality of the second expansion strut pair forming a second expansion column; a first connecting strut including a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section, the first connecting strut proximal section being coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section being coupled to the proximal end of the second expansion strut pair of the second expansion column, a plurality of the first connecting strut forming a first connecting strut column that couples the first expansion column to the second expansion column, the first connecting strut intermediate section being non-parallel to the first connecting strut proximal and distal sections, wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.	23. A stent in a non-expanded state, comprising: a first expansion column formed of a plurality of first expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to

	the fifth expansion strut; a second expansion column formed of a plurality of second expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut; and a first connecting strut column formed of a plurality of first

	connecting struts, each connecting strut of the first connecting strut column including a connecting strut proximal section, a connecting strut distal section and a connecting strut intermediate section, a first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the first expansion strut column, and a first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the second expansion strut column, and a second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the first expansion strut column, and a second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the second expansion strut column, the first connecting strut intermediate section being non-parallel to the first connecting strut proximal and distal sections wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.

Exhibit 11

[redacted]

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6203569

Class 623 Subclass 1.15

ISSUE CLASSIFICATION

SCANNED

UTILITY SERIAL NUMBER	PATENT DATE MAR 20 2001	PATENT NUMBER

SERIAL NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT	EXAMINER
08/883,501	06/27/97	623	1.15	3738	

APPLICANT(S)

BANDULA WIJAY, FRIENDSWOOD, TX.

CONTINUING DATA******** ********** **********
VERIFIED THIS APPLN IS A CON OF 08/582,657 01/04/96

C.K.

FOREIGN/PCT APPLICATIONS********
VERIFIED

CK

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FOREIGN FILING LICENSE GRANTED 9/30/97 ***** SMALL ENTITY *****

Foreign priority claimed 35 USC 119 conditions met / Verified and Acknowledged (Examiner's Initials)	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
☐ yes ☑ no / ☐ yes ☐ no — C.K.		X	4	29	6	$$04.00	WIJAY-1

ADDRESS

STEVE ROSENBLATT
ROSENBLATT & REDANO
ONE GREENWAY PLAZA
SUITE 500
HOUSTON TX 77046

TITLE

FLEXIBLE STENT

U.S. DEPT. OF COMM./ PAT. & TM—PTO-436L (Rev.12-94)

PARTS OF APPLICATION FILED SEPARATELY

Applications Examiner

NOTICE OF ALLOWANCE MAILED: 11-30-00

Choon P. Koh
Assistant Examiner

CLAIMS ALLOWED: Total Claims 26; Print Claim 1

ISSUE FEE: Amount Due 620; Date Paid 1/22/01 PAID

David J. Isabella
Primary Examiner

Primary Examiner

DRAWING: Sheets Drwg. 4; Figs. Drwg. 11; Print Fig. 1, 7, 8

PREPARED FOR ISSUE

ISSUE BATCH NUMBER 148

Label Area

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PTO-436L

ISSUE FEE IN FILE

ANW

(FACE)

BSC-J007894

BSC-C 017028

08/582657

ISSUE CLASSIFICATION | Class | Subclass

UTILITY SERIAL NUMBER 08/582657	PATENT DATE	PATENT NUMBER

SERIAL NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT	EXAMINER
08/582,657	01/04/96	128 c. 23	1	330 B	B/J

APPLICANTS

BANDULA WIJAY, FRIENDSWOOD, TX.

CONTINUING DATA********

VERIFIED

None filed

ABANDONED

FOREIGN/PCT APPLICATIONS********

VERIFIED

None filed

FOREIGN FILING LICENSE GRANTED 03/21/96 ***** SMALL ENTITY *****

Foreign priority claimed / 35 USC 119 conditions met / Verified and Acknowledged (Examiner's initials)	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
☐ yes ☑ no / ☐ yes ☐ no	→	TX	4	26	2	$441.00	WIJAY-05

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TITLE

FLEXIBLE STENT

U.S. DEPT. OF COMM./ PAT. & TM—PTO-436L (Rev.12

PARTS OF APPLICATION FILED SEPARATELY	Applications Examiner
NOTICE OF ALLOWANCE MAILED	Assistant Examiner
ISSUE FEE: Amount Due / Date Paid	Primary Examiner
Label Area	PREPARED FOR ISSUE

CLAIMS ALLOWED: Total Claims / Print Claim

DRAWING: Sheets Drwg. / Figs. Drwg. / Print Fig.

ISSUE BATCH NUMBER

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(FACE)

08/582657

Date Entered or Counted

PATENT APPLICATION

08582657

CONTENTS

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INITIALS _____

Date Received or Mailed

BOX AF

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	2.	IDS	1-4-96
	3.	Suppl IDS	2-13-96
	4.	Supp! I.D.S.	4-29-96
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	6.	Amdt A (Cm 13/5)	12-9-96
	7.	Suppl Amdt B	12-23-96
3/88	8.	Final Rej - 3 mos	4.8.97
	9.	Amdt C (1ME)	6-9-97
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PATENT APPLICATION

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INITIALS

ABANDONED

Date Entered or Counted

CONTENTS

Date Received or Mailed

ABN

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	12.	Pre Amdt D	6/27/97
9/14R	13.	Ltr 3mos	9-18-98
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7/99	15.	ABANDONED	7/30/99
	16.	Change of Add	10-25-99
	17.	Amdt Ltr	10-25-99
	18.	Ltr CPA	2-7-00
11-22	19.	Notice of Allowability	11-22-00
2/9/01	20.	Formal Drawings (4 sht(s)) set 1	1/22/01
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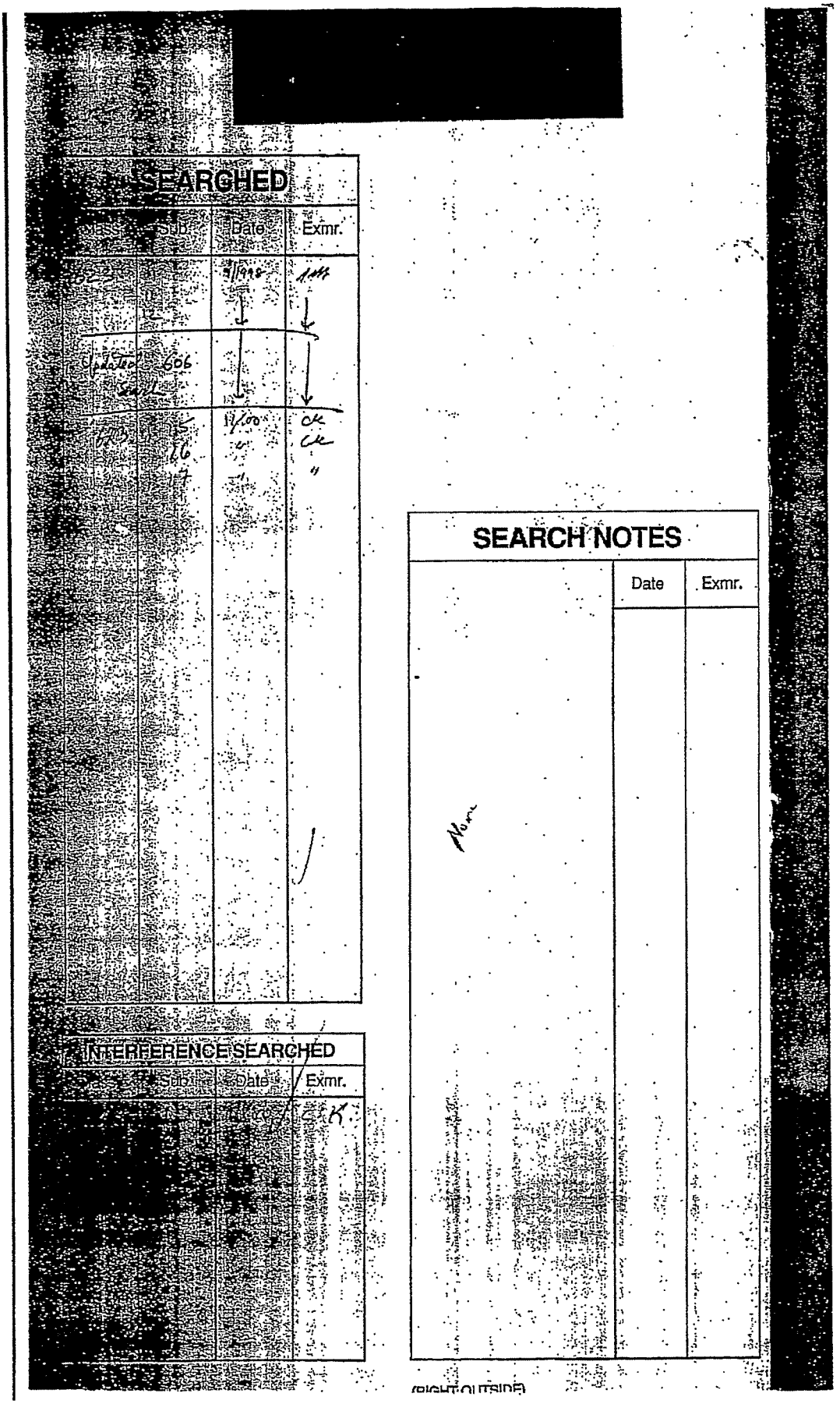

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SYMBOLS

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= ..... Allowed
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+ ..... Restricted
N ..... Non-elected
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A ..... Appeal
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EXAMINER		56	3-12-96
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INDEX OF CLAIMS

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SYMBOLS

✓	Rejected
=	Allowed
- (through centerline)	Cancelled
+	Restricted
R	Non-elected
I	Interference
A	Appeal
O	Objected

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US006203569B1

(12) **United States Patent**
Wijay

(10) **Patent No.: US 6,203,569 B1**
(45) **Date of Patent: *Mar. 20, 2001**

(54) **FLEXIBLE STENT**

(76) Inventor: Bandula Wijay, 1903 Carriage Creek Dr., Friendswood, TX (US) 77546

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 08/883,801

(22) Filed: Jun. 27, 1997

Related U.S. Application Data

(63) Continuation of application No. 08/582,657, filed on Jan. 4, 1996.

(51) Int. Cl.[7] A61F 2/06

(52) U.S. Cl. 623/1.15; 623/1.16; 623/1.17

(58) Field of Search 623/1, 11, 12, 623/1.15, 1.16, 1.17

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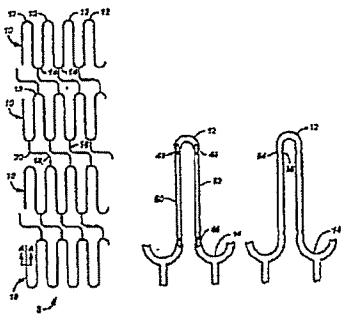
Primary Examiner—David J. Isabella
Assistant Examiner—Choon P. Koh
(74) *Attorney, Agent, or Firm*—Duane, Morris & Heckscher LLP

(57) **ABSTRACT**

A stent is disclosed which comprises generally of ring having, in the preferred embodiment, crossties that have flexibility by having at least one bend. The rings themselves have predetermined stress-relieving points to predispose, by stress relief, particular segments of each ring to bend upon application of an expansion force such as by a balloon or by other means. In the preferred embodiment, the individual rings have notches, reducing the cross-sectional areas at particular locations adjacent reversing bends such that upon radial expansion, bending occurs at these reduced cross-sectional areas to prevent stress from accumulating at the reversing bends.

26 Claims, 4 Drawing Sheets



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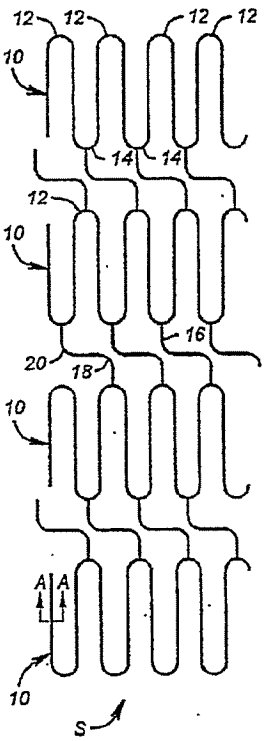

FIG. 1

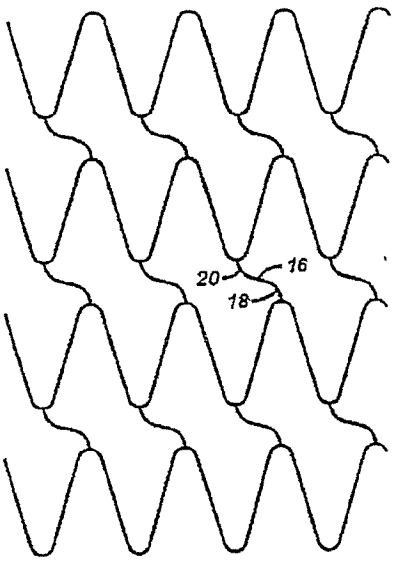

FIG. 2

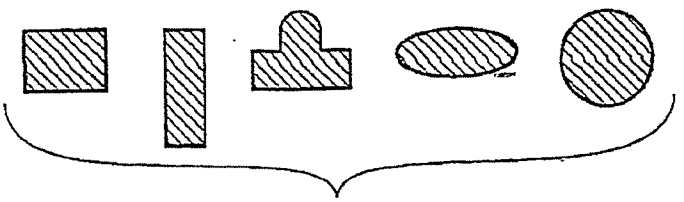

FIG. 3

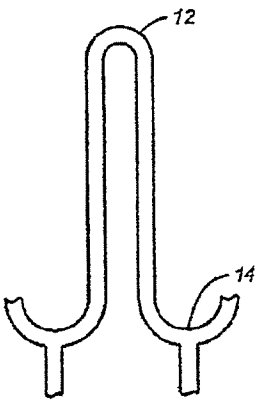

FIG. 4

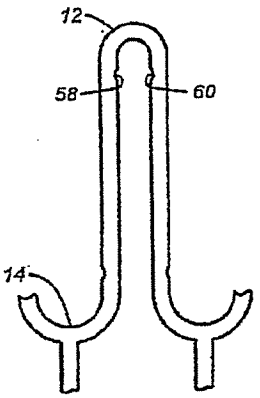

FIG. 5

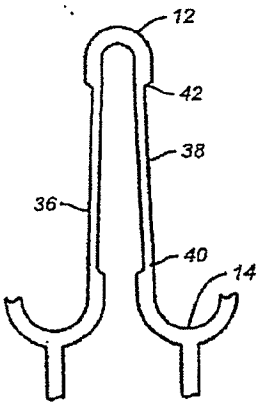

FIG. 6

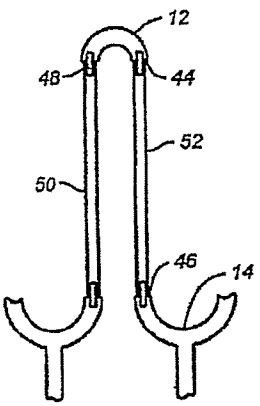

FIG. 7

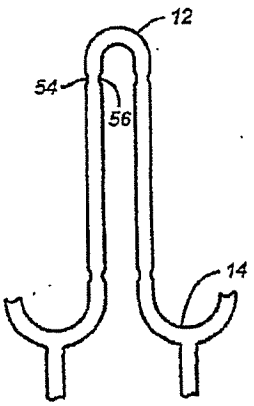

FIG. 8

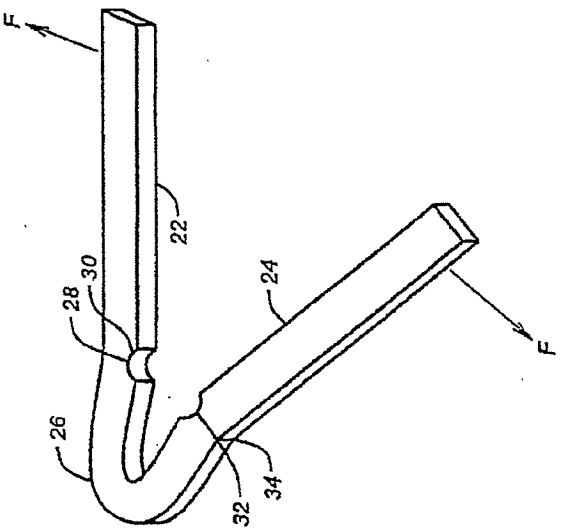

FIG. 10

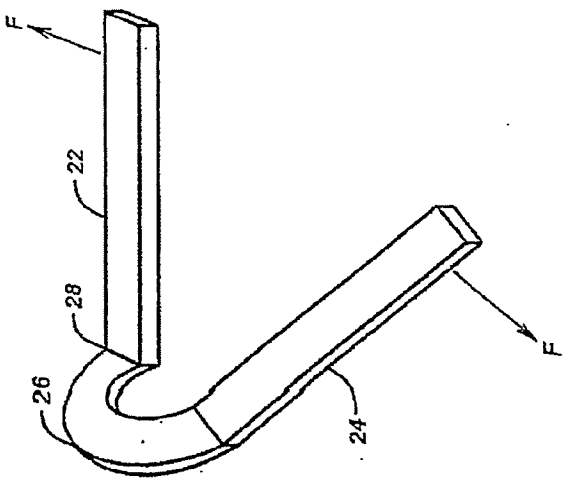

FIG. 9

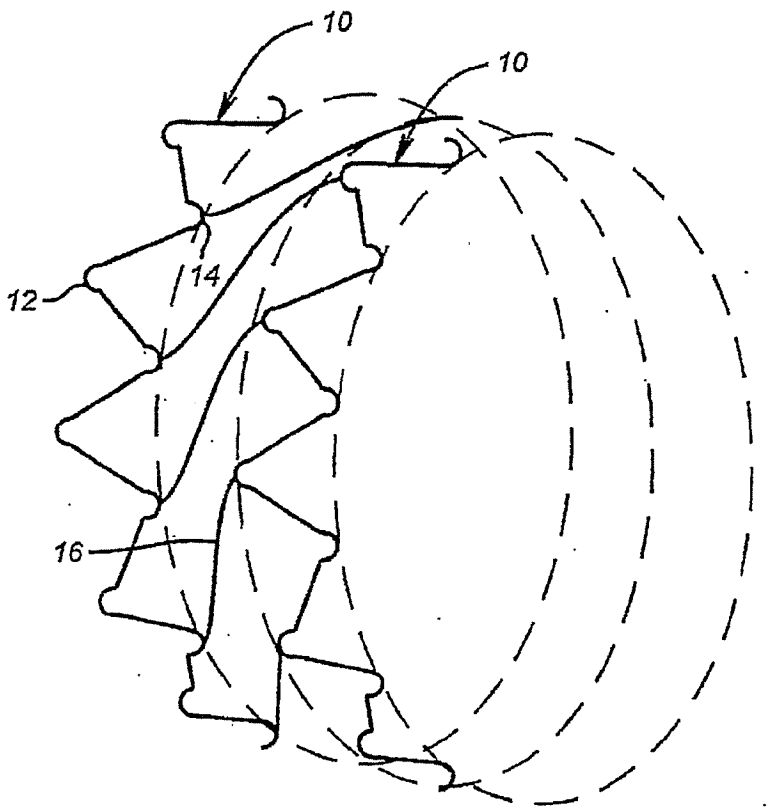

FIG. 11

FLEXIBLE STENT

This application is a continuation of copending application Ser. No. 08/582,657, filed on Jan. 4, 1996.

FIELD OF THE INVENTION

The field of this invention relates to vascular stents that can be delivered to a predetermined position and allowed to spring outwardly or, in the alternative, which can be expanded in place.

BACKGROUND OF THE INVENTION

Vascular stents are structures that are designed to maintain the patency of a vessel in the body. The stent provides internal support to allow the circulation to proceed therethrough. Stents can be used in the vascular system in ureters, bile ducts, esophagus, and in many other tubular structures in the human body.

Stents can be tubular or can be made from wire. Stents are typically made from a metal or polymeric substance or a metal coated with polymers which are biocompatible or contain heparin to reduce blood clotting or other tissue reactions. Many prior designs have used a coil approach where a wire is helically wound on a mandrel. Yet other designs have evolved—braided wire mesh and angulated wire forms wrapped on a spindle to form a coil.

U.S. Pat. No. 5,292,331 by Boneau and U.S. Pat. No. 5,403,341 describe such wire forms. These devices have very poor radial support to withstand the hoop strengths of the artery or vein and further are not suitable for arteries that are bent or curved or for long lesions; multiple stents are required. These designs do not provide any support to hold the wall of the artery, other than the memory of the metal.

Wall Stent, produced by Pfizer Inc., is a braided wire tube. Although this stent is flexible so as to be placed in curved arteries or veins and other body cavities, it does not have any radial strength imparted to it by design.

Wiktor, U.S. Pat. No. 4,649,922; 4,886,062; 4,969,458; and 5,133,732 describe a wire form stent. He describes stents made of wire helix made of a preformed wire which is in the sinusoidal form, in which either all or some of the adjacent strands are connected.

Arthus Fontaine, U.S. Pat. No. 5,370,683, also describes a similar device where a flat wire form of sinusoidal shape is wound on a mandrel to form a helical coil. the wire bends are "U" shaped and are connected to alternate "U"-shaped bands.

Allen Tower, U.S. Pat. Nos. 5,217,483 and 5,389,106 describes a similar device where the wire is preformed to a sinusoidal shape and subsequently wound on a mandrel to form a helical coil.

All of the above-described art fails to provide radial support. The pre-shaped wire form (sinusoidal in most of the prior art) is wrapped on a mandrel to form a coil. However, the forces imported by the vessel wall's hoop strength are radially inward. In other words, the force is acting perpendicular to the plane of the U-shaped wire form. This means that the bends that are in the wire add no structural strength to the wire form to support the force produced by the wall, which is radially inward.

When we examine the simple coils, such as taught in Scott U.S. Pat. No. 5,383,928 or Gene Samson U.S. Pat. No. 5,370,691 or Rolando Gills U.S. Pat. No. 5,222,969, it is apparent that the spring coil will withstand substantial radial forces due to the vessel wall; however, all these stents are

bulky in their pre-expanded form and are hard to place in small and curved arteries or veins of the body. Also, a major disadvantage of this design is that when the coil stent is placed in a curved artery or vein, it forms an "accordion" shape whereby some strands in the outer radius are spread and those of the inner radius are gathered. Spring coils can also "flip" to form a flat structure when a longitudinal force is applied on one side of the stent.

The other types of stents that have been developed are tube stents. Palmer, U.S. Pat. No. 4,733,665; 4,739,762; 7,776,337; and 4,793,348 describe such a tube stent of slotted metal tube. The slotted metal tube is expanded by a high-pressure balloon to implant the stent into the inside wall of the artery or vein.

Joseph Weinstein, U.S. Pat. No. 5,213,561 describes a similar stent made of tubular materials with slots cut into it. On expansion using a balloon, it forms a structure with diamond-shaped slots.

Henry Wall, U.S. Pat. No. 5,266,073 also describes a stent, tubular, that has slots machined into it. When expanded, the edges of the stent lock to form a cylinder. Not only is this device stiff and can only be used for short lesions, but also the diameter cannot be adjusted to meet the exact needs of the particular vessel but it is fixed to the predetermined sizes.

Lau and Hastigan, U.S. Pat. No. 5,344,426 describes a slotted tubular stent that has a structure similar to Henry Wall's but has provided prongs that will lock in as the stent is expanded.

Michael Marin, U.S. Pat. No. 5,397,355 also describes a tubular slotted stent with locking prongs.

U.S. Pat. No. 5,443,500 illustrates the use of square openings with rectangular prongs that stick therethrough to lock the stent. This design, as well as other locking mechanisms, generally have resulted in very stiff stents because of the use of a tubular-type grid construction. Further, the locking devices have resulted in sharp outwardly oriented tabs which are used for the locking, which could cause vascular damage.

All the above-described tube stents, although typically providing substantial radial support when expanded, are not flexible enough to be placed in curved vessels. Arteries and veins in the human body are mostly curved and are tapered. As such, these tube stents suffer from this main disadvantage.

European patent document 042172982 employs wires that are doubled up and whose ends are snipped off to make a given joint. Such doubling up at the junction of two elements with snipped off free ends creates a potential puncture problem upon radial expansion. The sheer bulk of the doubled up wires makes them rotate radially outwardly away from the longitudinal centerline of the stent, while the plain ends on such an arrangement which are snipped off offer the potential of sharp points which can puncture or damage the intima. On the other hand, the apparatus of the present invention, employing sharp angles, as defined, avoids this problem in an embodiment which illustrates a continuous wire or wire-like member bent into a sharp angle. This type of structure alleviates the concerns of sharp edges, as well as the tendency of a doubled up heavy joint to rotate outwardly toward the intima upon radial expansion of the stem. as would be expected in the EPO reference 042172982.

Often these stents are layered with polymeric sheaths that are impregnated with biocompatible substances or can be coated with heparin or hydrogel. Most sheath-type coatings

reduce endothelial cell growth through the stent, which is a major requirement in successful stenting of body cavities such as arteries and veins.

Several parameters in design of stents are important. Of the more important parameters is the issue of recoil. Recoil deals with the memory of the stent material which, generally speaking, upon expansion in the blood vessel will want to recoil back to its original shape. This can be problematic because it is desirable for the stent, once expanded, to remain in good contact with the vessel wall to avoid longitudinal shifting. Furthermore, any recoil constricts the flow passage and presents a greater portion of the stent in the blood flowpath, thus creating additional complications due to the turbulence which ensues.

Related to the concern regarding recoil is another concern regarding component twist. This phenomenon generally occurs when the cross-sectional area of the components is rectangular, such as when the stent is manufactured from a cylindrical piece which is then cut by lasers or other means to form the particular pattern. Particularly in the honeycombed designs involving the use of square or rectangular element cross-sections, radial expansion of such stents generally results in a twist of the component segments such that they extend into the flowpath in the artery or vein. Again, this causes turbulence which is undesirable.

Related to the problem of recoil or constriction after expansion is the ability of the stent to anchor itself in the vascular wall. An anchoring system that does not cause trauma is a desirable feature not found in the prior art.

Yet other considerations which are desirable in a stent not found in the prior art is the flexibility to be maneuvered around bends in the vascular system, coupled with the ability to conform to a bend without kinking or leaving large open areas. The stents of the present invention have the objective of addressing the issue of recoil, as well as providing an anchoring mechanism to fixate the stent once set. Several of the designs incorporate flexibility to allow the stent to follow a bend or curve in a vascular flowpath while at the same time providing sufficient radial deformation to ensure proper fixation while minimizing angular twisting movements of the stent components to minimize turbulence through the stent.

In a recent article appearing in late 1995, by Dr. Donald S. Baim, entitled "New Stent Designs," a description is given of the ideal endovascular prosthesis. There, Dr. Baim indicates that the ideal stent should have low implantation profile with enhanced flexibility to facilitate delivery. He goes on to say that the stent should be constructed from a noncorrosive, nonthrombogenic radiopaque alloy and have expanded geometry which maximizes radial strength to resist vascular recoil. The ideal stent described by Baim is further described as having a wide range of diameters and lengths. Dr. Baim concludes that it is unlikely that any current designs satisfy all these requirements. Thus, one of the objectives of the present invention is to go further than the prior designs in satisfying the criteria for the ideal designs as set forth by Dr. Baim in his recent article.

SUMMARY OF THE INVENTION

A stent is disclosed which comprises generally of ring having, in the preferred embodiment, crossties that have flexibility by having at least one bend. The rings themselves have predetermined stress-relieving points to predispose, by stress relief, particular segments of each ring to bend upon application of an expansion force such as by a balloon or by other means. In the preferred embodiment, the individual rings have notches, reducing the cross-sectional areas at particular locations adjacent reversing bends such that upon radial expansion, bending occurs at these reduced cross-sectional areas to prevent stress from accumulating at the reversing bends.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates the stent of the present invention in an unrolled condition prior to expansion.

FIG. 2 is the stent shown in FIG. 1 in an unrolled condition after expansion.

FIG. 3 is a section along lines A—A of FIG. 1 and illustrates several different cross-sectional shapes that can be used for the stent illustrated in FIG. 1.

FIG. 4 is a detailed view of the stent in FIG. 1, shown without any cross-sectional changes to the undulating design of the ring structure illustrated in FIG. 1.

FIG. 5 is similar to FIG. 4 except that it employs singular notches adjacent reversing bends.

FIG. 6 employs a change in the cross-sectional shape taking place adjacent each reversing bend.

FIG. 7 illustrates a joint involving a transverse tab adjacent the reversing bends.

FIG. 8 involves opposed notches on each side of the wire adjacent a reversing bend.

FIG. 9 illustrates what occurs on radial expansion of each of the rings without the use of a stress-relief mechanism such as a notch or a cut-out.

FIG. 10 illustrates the action upon radial expansion using a notch and its effect on the reversing bend.

FIG. 11 is a perspective view of the stent shown in FIG. 2 in the expanded position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 shows, in flattened out form, a stent S which is unrolled along its longitudinal axis. The stent S has a series of rings 10 which are preferably of a wire material (preferably stainless steel, nickel-titanium alloys, tantalum alloys) bent in a series of reversing undulations 12 and 14. The wire can be coated with polymer such as polyethylene, polytetrafluoroethylene (Teflon®), or polylactates containing heparin or drugs or radioactive material. The bends 12 may have a similar radius or may vary as among bends 12 or as among bends 14. In other words, each of the bends 12 may be identical to each other. Each of the bends 14 may be identical to each other. Each bend 12 may be identical to each bend 14. One bend 12 can be different from another bend 12, which is in turn also different from another bend 14, or any combinations of the above. While rounded bends are shown as 12 and 14, other shapes can be used to create a generally undulating pattern, such as sharp bends which generally form a V-shape. Connecting each row 10 is one or more crossties 16. In the preferred embodiment, the crossties 16 have flexibility in that they have at least one bend 18, while a double bend, such as including 18 and 20, is preferred for the construction of the crossties 16. One or more crossties can be used which connect a bend 14 to its opposing bend 12. Thus, as shown in FIG. 1, the crossties 16, looking from bottom to top, make a bend to the left and a bend to the right on their way from reverse bend 12 to a reverse bend 14. One or more crossties 16 can be used between rings 10 up to a maximum where every reversing bend, such as 14, is connected to an adjacent but offset circumferentially reversing bend 12.

FIG. 2 illustrates the stent S in a radially expanded form, illustrating that the crossties 16 continue to retain flexibility because of the reversing bends 18 and 20. Thus, the longitudinal flexibility of the stent S is retained, even in the expanded position. The use of the crossties with, at minimum, a single bend gives them flexibility. The design involving rings 10 connected by crossties 16 prevents stiffness experienced in some prior designs that had a particular longitudinal segment with undue stiffness giving the stent S a "backbone," thus making it unduly stiff longitudinally. Use of the flexible crossties 16 also provides flexibility for relative rotation between rings 10 while the expansion is taking place. Flexibility is also provided in the longitudinal direction as the crossties 16 may elongate in that direction without putting the stent S into a kink or a longitudinal bind.

FIG. 3 illustrates alternative cross-sectional shapes for the wire cross-section which makes up each of the rings 10 and/or the crossties 16. Thus, FIG. 3 illustrates squares, rectangles, circles, ovals, and composite shapes.

One of the concerns with an undulating structure, such as illustrated in FIG. 1, is the reversing bends 12 or 14, unless some provisions are made, experience undue stress and are even prone to bending out of their plane when the stent is radially expanded. This phenomenon is illustrated in FIG. 9. There, a pair of straight segments 22 and 24 are joined together by a reversing bend 26. As illustrated in FIG. 9, the cross-sectional area of the segments 22 and 24 are rectangular, one of the shapes shown in FIG. 3. It should be noted that other cross-sections, apart those illustrated in FIG. 3, can be used without departing from the spirit of the invention.

With no significant cross-sectional change occurring at the transition or near the transition 28 between the reverse bend 26 and the segments 24 or 22, the stress is transferred to the reverse bend 26 when an expansion force F tries to radially expand the stent S by moving segments 22 and 24 apart. Depending on the amount of stress induced, a bending occurs, as shown in FIG. 9, where the reverse bend 26 bends out of plane so that it is no longer in alignment with the segments 22 and 24, which was its condition prior to the application of force F.

FIG. 10 shows the contrast of the behavior of the reverse bend 26 when a notch 30 is placed adjacent the transition 28 between the reverse bend 26 and the segment 22 and a similar notch 32 is placed near transition 34 between the reverse bend 26 and the segment 24. What results is a reduced cross-sectional area at transitions 28 and 34. Thus, when force F is applied to the segments 22 and 24, there is a permanent bending occurring at the zone of least cross-sectional area, i.e., transitions 28 and 34, with their respective notches 30 and 32. Accordingly, the stress from radial expansion of a ring 10 as illustrated in FIG. 1 is absorbed by a bending or deformation at the transitions 28 and 32, thus minimizing if not eliminating the applied stress to the reverse bend 26 after radial expansion of the stent S by expanding all of the rings 10. This type of structure illustrated in FIG. 10 can be employed in the unrolled stent shown in FIGS. 1 and 2.

Other alternative mechanisms for reducing the stress at the reverse bend are illustrated in FIGS. 5–8. It should be noted that the features illustrated in FIGS. 5–8 are to be found in the stent shown in FIGS. 1 and 2; however, in order to show the overall layout of the stent S, FIGS. 1 and 2 are not sufficiently magnified so that these details can be seen. However, FIGS. 5–8 represent a greater magnification of adjacent reverse bends, such as 12 and 14.

In FIG. 6, the connecting segments 36 and 38 have a smaller cross-sectional area than the cross-sectional area at the reverse bends 12 and 14, thus creating zones of transition of cross-section 40 adjacent reverse bend 14 and 42 adjacent reverse bend 12. This construction is typical for each of the rings 10 of a particular stent. It should be noted that the various features illustrated in FIGS. 5–8 can be used uniformly throughout the stent or mixed and matched for a desired effect.

The detail in FIG. 7 illustrates a cross-sectional area transition point 44 and 46, respectively adjacent reverse bends 12 and 14. Here, there is not only a transition cross-sectional area but transverse tabs 48 are used to secure the joint between segments 50 and 52, which have a smaller cross-sectional area than the cross-sectional area of reverse bends 12 and 14.

FIG. 8 illustrates the use of opposed notches 54 and 56 adjacent the entrance and exit to each reverse bend 12 and 14. FIG. 5 illustrates the use of similar notches 58 and 60 at the entrance and exit of each reverse bend 12 and 14. The difference between FIG. 5 and FIG. 8 is that in FIG. 8, the notches 54 and 56 oppose each other at the entrance and exit of each reverse bend 12 or 14, while in FIG. 5 the notches can be interiorly located, as shown in FIG. 5, or in the alternative, exteriorly located at the entrance and exit to each reverse bend 12 and 14. It should be noted that the changes in cross-sectional area do not need to be literally at the point of transition between the rounded portion of a reverse bend 12 or 14 and the straight segment which adjoins the reverse bends. However, the preferred location is at that transition. Locating the cross-sectional area change before entering the transition from the straight segment to the curved segment is also possible, depending on the degree of stress relief desired.

FIG. 11 illustrates the stent S shown in unrolled form in FIGS. 1 and 2 in a perspective view after radial expansion. It should be noted that the crossties 16 retain their flexibility, even after expansion, and that the reverse bends 12 and 14 have not buckled out of the cylindrical surface defined by the expanded stent S shown in FIG. 11. The buckling feature, which can occur in prior designs without the stress relief mechanism, is illustrated in FIG. 9.

FIG. 4 illustrates that it is within the purview of the invention to use a plurality of rings 10 connected by flexible crossties 16 without the change in cross-sectional area occurring at the reverse bends 12 and 14. While the embodiments in FIGS. 5–8 are preferred, it is within the purview of the invention to provide a stent with a multiplicity of rows 10 of undulating wire components which are connected by one or more crossties 16, each of which have at least one bend so that upon radial expansion into the position shown in FIGS. 2 and 11, the crossties 16 continue to retain flexibility in at least one but preferably more directions. Thus, the individual rings 10 have longitudinal flexibility and may rotate to some degree with respect to each other, all to conform to the tortuous path in which the stent S may be placed. By adding the change in the cross-sectional area feature, as shown in FIGS. 5–8, by using one or more of those features in a single stent, a stent is produced that is flexible, yet when expanded, retains its flexibility and is not subjected to stress to a significant degree at reversing bends after complete radial expansion. By focusing the stress occurring during radial expansion to a particular point outside the reversing bend, a simple-to-make construction occurs which addresses the concerns of some of the prior art designs which have tackled this problem by using varying degrees of curvature, such as European application No.

0662307, assigned to Advanced Cardiovascular Systems. This design, with the flexible crossties 16, represents a considerably more flexible design than rolled up coil springs such as that illustrated in U.S. Pat. No. 4,969,458. Crossties which are essentially straight, such as those illustrated in U.S. Pat. No. 5,421,955, do not afford the flexibility realized by the stent S of the present invention. It should be noted that as more bulk is presented at the transition between segments such as 22 and 24 in FIG. 9, the more likely is the bending to occur when subjected to radial expansion, as illustrated schematically by force F. Thus, designs that use doubled up wires at the apex, such as European application No. 0421729, assigned to Medtronic, exacerbate the bending results shown in FIG. 9, as well as increasing the stiffness of the stent and the force necessary for radial expansion of each of its individual rings. Additionally, by use of crossties which are coiled springs which protrude out of the cylindrical surface defined by the stent S, additional complications are created since the crossties will intrude into the vascular wall, creating additional irritation to the patient or worse damage if there is penetration of the vascular wall.

Accordingly, the above-described stent S of the present invention has the advantages of flexibility in view of the unique crossties which are used. The crossties remain in the cylindrical surface defined by the shape of the stent S, even upon radial expansion. The crossties 16 retain their flexibility, even after full radial expansion occurs. By use of the cross-sectional area changes, the applied stresses from radial expansion are focused to this transition zone as opposed to other places, such as the return bends. By focusing the deformation to the transition zone, stress is minimized or reduced in the reverse bend section, such as 12 or 14, and further the tendency of the reverse bends such as 12 or 14 to protrude out of the cylindrical surface defined by the stent S is greatly reduced, if not eliminated.

The foregoing disclosure and description of the invention are illustrative and explanatory thereof, and various changes in the size, shape and materials, as well as in the details of the illustrated construction, may be made without departing from the spirit of the invention.

What is claimed is:

1. A stent comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring compriss a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends and at least two cross-sectional areas identified by at least one cross-sectional change location, said wire member forming an undulating panern;

at least one crosstie connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed therein;

the cross-sectional area of said wire member changes adjacent at least one of said reversing bends;

said wire member which comprises each said rings, when expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends; and

said reversing bends remain generally aligned to said cylindrical shape defined by said rings after radial expansion due to bending at said cross-sectional change locations.

2. A stent, compising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends, and at least two cross-sectional areas defined by at least one cross-sectional change location, said wire member forming an undulating pattern;

at least one crosstie connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed therein;

said wire member having at least one straight section between said reversing bends;

the cross sectional area of said wire member changes in said straight section and adjacent said reversing bends;

said wire member which comprises each said rings, when expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends; and

said reversing bends remain generally aligned to said cylindrical shape defined by said rings after radial expansion due to bending at said cross-sectional change locations.

3. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends, said wire member forming an undulating pattern, said wire member having at least one cross-sectional area;

at least one crosstie connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed therein;

the wire member is formed having a notch wherein the cross-sectional area of the wire member changes at a notch location;

said notch is located adjacent at least one of said reversing bends.

4. The stent of claim 3, wherein:

said change in cross-section is accomplished by opposed notches.

5. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having reversing bends forming an undulating pattern;

at least one crosstie connecting adjacent rings wherein said crosstie is disposed in general alignment with a longitudinal axis defined by said rings; and

said wire member is formed having a notch adjacent at least one of said reversing bends which defines a change in cross-sectional area.

6. The stent of claim 5, wherein:

said change in cross-sectional area is accomplished by opposed notches.

7. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing

bends, said wire member forming an undulating pattern; and having at least two cross-sectional areas identified by at least one cross-sectional change location; and

at least one cross-tie having said connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed between said ends to allow said crosstie to flex as said rings expand while remaining within the confines of said cylindrical shape; and

the cross-sectional area of said wire member changes adjacent at least one of said reversing bends.

8. The stent of claim 7, wherein:

said wire member changes cross-section adjacent each said reversing bend.

9. The stent of claim 8, wherein:

said wire member changes cross-section on both sides of each said reversing bend.

10. The stent of claim 7, wherein:

said wire member which comprises said rings, when said rings are expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends.

11. The stent of claim 1, further comprising:

a plurality of non-overlapping crossties each having at least two bends.

12. The stent of claim 11, wherein:

said bends define at least two slope changes in said crossties.

13. The stent of claim 12, wherein:

each crosstie connects a reversing bend in one of said rings to the next adjacent circumferentially offset reversing bend on an adjacent ring.

14. The stent of claim 1, wherein:

said at least one crosstie comprises at least two reversing bends located remotely from said end of said crosstie.

15. The stent of claim 7 wherein:

said at least one crosstie comprises at least two reversing bends located remotely from said ends of said crosstie; and

said bends define a turn of no less than about 90°.

16. The stent of claim 15. wherein:

said crosstie having a first end offset circumferentially from a second end.

17. The stent of claim 15, wherein that portion of said crossties extending between said first and second ends and up to said bends of said crosstie are in substantial longitudinal alignment with the longitudinal axis of said cylindrical shape.

18. The stent of claim 3, wherein:

said wire-like member has straight sections between said reversing bends;

said straight sections have a smaller cross-sectional area than the cross-sectional area through said reversing bends.

19. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends; said wire member forming an undulating pattern and having at least one cross-section;

at least one crosstie connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed therein; and

said wire member having at least one straight section between said reversing bends;

the cross-section of said wire member changes in said straight section and adjacent said reversing bends.

20. The stent of claim 9, wherein:

said straight section has a smaller cross-sectional area than the cross-sectional area through an adjacent said reverse bend.

21. The stent of claim 19, wherein:

said wire member changes cross-section adjacent each said reversing bend.

22. The stent of claim 19, wherein:

said wire member changes cross-section on both sides of each said reversing bend.

23. The stent of claim 19, wherein:

said wire member which comprises said rings, when said rings are expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends.

24. A stent of claim 19, further comprising:

a plurality of non-overlapping crossties each having at least two bends.

25. The stent of claim 24, wherein:

said bends define at least two slope changes in said crossties.

26. The stent of claim 25, wherein:

each crosstie connects a reversing bend in one of said rings to the next adjacent circumferentially offset reversing bend on an adjacent ring.

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PATENT APPLICATION SERIAL NO. 07/582657

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PATENT AND TRADEMARK OFFICE
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U.S. PATENT APPLICATION

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT
08/582,657	01/04/96	128	3301

APPLICANT

BANDULA WIJAY, FRIENDSWOOD, TX.

CONTINUING DATA********
VERIFIED

FOREIGN/PCT APPLICATIONS********
VERIFIED

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STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS	FILING FEE RECEIVED	ATTORNEY DOCKET NO.
TX	4	26	2	$441.00	WIJAY-05

ADDRESS

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TITLE

FLEXIBLE STENT

This is to certify that annexed hereto is a true copy from the records of the United States Patent and Trademark Office of the application which is identified above.

By authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

Date Certifying Officer

BSC-J007915

BSC-C 017049

08/582657

Docket No. WIJAY-05

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of **Bandula Wijay** for his invention entitled: **Flexible Stent.**

1. This new application is an original.

2. Papers enclosed which are required for filing date under 37 CFR 1.53(b):

13	Pages of specification
05	Pages of claims
01	Pages of abstract
04	Sheet of drawing (in triplicate)

3. Enclosed are the follwing documents filed inconnection with this application:

Combined Declaration and Power of Attorney signed by the inventor
Verified Statement Claiming Small Entity Status
Information Disclosure Statement
Form PTO-1449
References Cited

4. The inventorship for all claims in this application is the same.

5. The application is in the English language.

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on **January 4, 1996**, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EM510596643US** addressed to the Commissioner of Patents & Trademarks, Washington, D. C. 20231.

Steve Rosenblatt

The fee calculation for a regular application is as follows:

CLAIMS AS FILED

	Number Filed				Number Extra		Rate		Basic Fee (37 C.F.R. 1.16(a) $750
Total Claims	26	-	20	=	6	x	$22	=	132
Independent Claims	2	-	3	=	0	x	$78	=	0
Multiple Dependent Claims (if any)						+	$240		
Total Filing Fee									$882
Filing Fee Less 50%									$441

7. Our check in the amount of $441 is enclosed for the filing fee.

8. The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Deposit Account No. 18-2020.

   37 CFR 1.16 (filing fees)
   37 CFR 1.16 (presentation of extra claims)
   37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application).
   37 CFR 1.17 (application processing fees)

9. Any overpayment is to be credited to Account No. 18-2020.

Respectfully submitted,

ROSENBLATT & REDANO, P.C.

January 4, 1996

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ABSTRACT OF THE DISCLOSURE

A stent is disclosed which comprises generally of ring having, in the preferred embodiment, crossties that have flexibility by having at least one bend. The rings themselves have predetermined stress-relieving points to predispose, by stress relief, particular segments of each ring to bend upon application of an expansion force such as by a balloon or by other means. In the preferred embodiment, the individual rings have notches, reducing the cross-sectional areas at particular locations adjacent reversing bends such that upon radial expansion, bending occurs at these reduced cross-sectional areas to prevent stress from accumulating at the reversing bends.

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08/582657

TITLE: FLEXIBLE STENT

INVENTORS: BANDULA WIJAY

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FIELD OF THE INVENTION

The field of this invention relates to vascular stents that can be delivered to a predetermined position and allowed to spring outwardly or, in the alternative, which can be expanded in place.

BACKGROUND OF THE INVENTION

Vascular stents are structures that are designed to maintain the patency of a vessel in the body. The stent provides internal support to allow the circulation to proceed therethrough. Stents can be used in the vascular system in ureters, bile ducts, esophagus, and in many other tubular structures in the human body.

Stents can be tubular or can be made from wire. Stents are typically made from a metal or polymeric substance or a metal coated with polymers which are biocompatible or contain heparin to reduce blood clotting or other tissue reactions. Many prior designs have used a coil approach where a wire is helically wound on a mandrel. Yet other designs have evolved--braided wire mesh and angulated wire forms wrapped on a spindle to form a coil.

U.S. Patent 5,292,331 by Boneau and U.S. Patent 5,403,341 describe such wire forms. These devices have very poor radial support to withstand the hoop strengths of the artery or vein and further are not suitable for arteries that are bent or curved or for long lesions; multiple stents are required. These designs do not provide any support to hold the wall of the artery, other than the memory of the metal.

Wall Stent, produced by Pfizer Inc., is a braided wire tube. Although this stent is flexible so as to be placed in curved arteries or veins and other body cavities, it does not have any radial strength imparted to it by design.

Wiktor, patent Nos. 4,649,922; 4,886,062; 4,969,458; and 5,133,732 describe a wire form stent. He describes stents made of wire helix made of a preformed wire which is in the sinusoidal form, in which either all or some of the adjacent strands are connected.

Arthus Fontaine, Patent No. 5,370,683, also describes a similar device where a flat wire form of sinusoidal shape is wound on a mandrel to form a helical coil. the wire bends are "U" shaped and are connected to alternate "U"-shaped bands.

Allen Tower, U.S. Patent Nos. 5,217,483 and 5,389,106 describes a similar device where the wire is preformed to a sinusoidal shape and subsequently wound on a mandrel to form a helical coil.

All of the above-described art fails to provide radial support. The pre-shaped wire form (sinusoidal in most of the prior art) is wrapped on a mandrel to form a coil. However, the forces imported by the vessel wall's hoop strength are radially inward. In other words, the force is acting perpendicular to the plane of the U-shaped wire form. This means that the bends that are in the wire add no structural strength to the wire form to support the force produced by the wall, which is radially inward.

When we examine the simple coils, such as taught in U.S. Patents Scott 5,383,928 or Gene Samson 5,370,691 or Rolando Gills 5,222,969, it is apparent that the spring coil will withstand substantial radial forces due to the vessel wall; however, all these stents are bulky in their pre-expanded form and are hard to place in small and curved arteries or veins of the body. Also, a major disadvantage of this design is that when the coil stent is placed in a curved artery or vein, it

forms an "accordion" shape whereby some strands in the outer radius are spread and those of the inner radius are gathered. Spring coils can also "flip" to form a flat structure when a longitudinal force is applied on one side of the stent.

The other types of stents that have been developed are tube stents. Palmer, U.S. Patent Nos. 4,733,665; 4,739,762; 7,776,337; and 4,793,348 describe such a tube stent of slotted metal tube. The slotted metal tube is expanded by a high-pressure balloon to implant the stent into the inside wall of the artery or vein.

Joseph Weinstein, U.S. Patent No. 5,213,561 describes a similar stent made of tubular materials with slots cut into it. On expansion using a balloon, it forms a structure with diamond-shaped slots.

Henry Wall, U.S. Patent No. 5,266,073 also describes a stent, tubular, that has slots machined into it. When expanded, the edges of the stent lock to form a cylinder. Not only is this device stiff and can only be used for short lesions, but also the diameter cannot be adjusted to meet the exact needs of the particular vessel but it is fixed to the predetermined sizes.

Lau and Hastigan, U.S. Patent 5,344,426 describes a slotted tubular stent that has a structure similar to Henry Wall's but has provided prongs that will lock in as the stent is expanded.

Michael Marin, U.S. Patent 5,397,355 also describes a tubular slotted stent with locking prongs.

U.S. Patent 5,443,500 illustrates the use of square openings with rectangular prongs that stick therethrough to lock the stent. This design, as well as other locking mechanisms, generally have resulted in very stiff stents because of the use of a tubular-type grid construction. Further, the locking devices have resulted in sharp outwardly oriented tabs which are used for the locking, which could cause vascular damage.

All the above–described tube stents, although typically providing substantial radial support when expanded, are not flexible enough to be placed in curved vessels. Arteries and veins in the human body are mostly curved and are tapered. As such, these tube stents suffer from this main disadvantage.

European patent document 042172982 employs wires that are doubled up and whose ends are snipped off to make a given joint. Such doubling up at the junction of two elements with snipped off free ends creates a potential puncture problem upon radial expansion. The sheer bulk of the doubled up wires makes them rotate radially outwardly away from the longitudinal centerline of the stent, while the plain ends on such an arrangement which are snipped off offer the potential of sharp points which can puncture or damage the intima. On the other hand, the apparatus of the present invention, employing sharp angles, as defined, avoids this problem in an embodiment which illustrates a continuous wire or wire–like member bent into a sharp angle. This type of structure alleviates the concerns of sharp edges, as well as the tendency of a doubled up heavy joint to rotate outwardly toward the intima upon radial expansion of the stem, as would be expected in the EPO reference 042172982.

Often these stents are layered with polymeric sheaths that are impregnated with biocompatible substances or can be coated with heparin or hydrogel. Most sheath–type coatings reduce endothelial cell growth through the stent, which is a major requirement in successful stenting of body cavities such as arteries and veins.

Several parameters in design of stents are important. Of the more important parameters is the issue of recoil. Recoil deals with the memory of the stent material which, generally speaking, upon expansion in the blood vessel will want to recoil back to its original shape. This can be problematic because it is desirable for the stent, once expanded, to remain in good contact with the vessel wall to

avoid longitudinal shifting. Furthermore, any recoil constricts the flow passage and presents a greater portion of the stent in the blood flowpath, thus creating additional complications due to the turbulence which ensues.

Related to the concern regarding recoil is another concern regarding component twist. This phenomenon generally occurs when the cross-sectional area of the components is rectangular, such as when the stent is manufactured from a cylindrical piece which is then cut by lasers or other means to form the particular pattern. Particularly in the honeycombed designs involving the use of square or rectangular element cross-sections, radial expansion of such stents generally results in a twist of the component segments such that they extend into the flowpath in the artery or vein. Again, this causes turbulence which is undesirable.

Related to the problem of recoil or constriction after expansion is the ability of the stent to anchor itself in the vascular wall. An anchoring system that does not cause trauma is a desirable feature not found in the prior art.

Yet other considerations which are desirable in a stent not found in the prior art is the flexibility to be maneuvered around bends in the vascular system, coupled with the ability to conform to a bend without kinking or leaving large open areas. The stents of the present invention have the objective of addressing the issue of recoil, as well as providing an anchoring mechanism to fixate the stent once set. Several of the designs incorporate flexibility to allow the stent to follow a bend or curve in a vascular flowpath while a the same time providing sufficient radial deformation to ensure proper fixation while minimizing angular twisting movements of the stent components to minimize turbulence through the stent.

In a recent article appearing in late 1995, by Dr. Donald S. Baim, entitled "New Stent Designs," a description is given of the ideal endovascular prosthesis. There, Dr. Baim indicates that the ideal stent should have low implantation profile

with enhanced flexibility to facilitate delivery. He goes on to say that the stent should be constructed from a noncorrosive, nonthrombogenic radiopaque alloy and have expanded geometry which maximizes radial strength to resist vascular recoil. The ideal stent described by Baim is further described as having a wide range of diameters and lengths. Dr. Baim concludes that it is unlikely that any current designs satisfy all these requirements. Thus, one of the objectives of the present invention is to go further than the prior designs in satisfying the criteria for the ideal designs as set forth by Dr. Baim in his recent article.

SUMMARY OF THE INVENTION

A stent is disclosed which comprises generally of ring having, in the preferred embodiment, crossties that have flexibility by having at least one bend. The rings themselves have predetermined stress-relieving points to predispose, by stress relief, particular segments of each ring to bend upon application of an expansion force such as by a balloon or by other means. In the preferred embodiment, the individual rings have notches, reducing the cross-sectional areas at particular locations adjacent reversing bends such that upon radial expansion, bending occurs at these reduced cross-sectional areas to prevent stress from accumulating at the reversing bends.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates the stent of the present invention in an unrolled condition prior to expansion.

Figure 2 is the stent shown in Figure 1 in an unrolled condition after expansion.

Figure 3 is a section along lines A–A of Figure 1 and illustrates several different cross–sectional shapes that can be used for the stent illustrated in Figure 1.

Figure 4 is a detailed view of the stent in Figure 1, shown without any cross–sectional changes to the undulating design of the ring structure illustrated in Figure 1.

Figure 5 is similar to Figure 4 except that it employs singular notches adjacent reversing bends.

Figure 6 employs a change in the cross–sectional shape taking place adjacent each reversing bend.

Figure 7 illustrates a joint involving a transverse tab adjacent the reversing bends.

Figure 8 involves opposed notches on each side of the wire adjacent a reversing bend.

Figure 9 illustrates what occurs on radial expansion of each of the rings without the use of a stress–relief mechanism such as a notch or a cut–out.

Figure 10 illustrates the action upon radial expansion using a notch and its effect on the reversing bend.

Figure 11 is a perspective view of the stent shown in Figure 2 in the expanded position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 1 shows, in flattened out form, a stent S which is unrolled along its longitudinal axis. The stent S has a series of rings 10 which are preferably of a wire material (preferably stainless steel, nickel–titanium alloys, tantalum alloys)–bent in a series of reversing undulations 12 and 14. The wire can be coated with

polymer such as polyethylene, polytetrafluoroethylene (Teflon®), or polylactates containing heparin or drugs or radioactive material. The bends **12** may have a similar radius or may vary as among bends **12** or as among bends **14**. In other words, each of the bends **12** may be identical to each other. Each of the bends **14** may be identical to each other. Each bend **12** may be identical to each bend **14**. One bend **12** can be different from another bend **12**, which is in turn also different from another bend **14**, or any combinations of the above. While rounded bends are shown as **12** and **14**, other shapes can be used to create a generally undulating pattern, such as sharp bends which generally form a V–shape. Connecting each row **10** is one or more crossties **16**. In the preferred embodiment, the crossties **16** have flexibility in that they have at least one bend **18**, while a double bend, such as including **18** and **20**, is preferred for the construction of the crossties **16**. One or more crossties can be used which connect a bend **14** to its opposing bend **12**. Thus, as shown in Figure 1, the crossties **16**, looking from bottom to top, make a bend to the left and a bend to the right on their way from reverse bend **12** to a reverse bend **14**. One or more crossties **16** can be used between rings **10** up to a maximum where every reversing bend, such as **14**, is connected to an adjacent but offset circumferentially reversing bend **12**.

Figure 2 illustrates the stent **S** in a radially expanded form, illustrating that the crossties **16** continue to retain flexibility because of the reversing bends **18** and **20**. Thus, the longitudinal flexibility of the stent **S** is retained, even in the expanded position. The use of the crossties with, at minimum, a single bend gives them flexibility. The design involving rings **10** connected by crossties **16** prevents stiffness experienced in some prior designs that had a particular longitudinal segment with undue stiffness giving the stent **S** a "backbone," thus making it unduly stiff longitudinally. Use of the flexible crossties **16** also provides flexibility

for relative rotation between rings 10 while the expansion is taking place. Flexibility is also provided in the longitudinal direction as the crossties 16 may elongate in that direction without putting the stent S into a kink or a longitudinal bind.

Figure 3 illustrates alternative cross-sectional shapes for the wire cross-section which makes up each of the rings 10 and/or the crossties 16. Thus, Figure 3 illustrates squares, rectangles, circles, ovals, and composite shapes.

One of the concerns with an undulating structure, such as illustrated in Figure 1, is the reversing bends 12 or 14, unless some provisions are made, experience undue stress and are even prone to bending out of their plane when the stent is radially expanded. This phenomenon is illustrated in Figure 9. There, a pair of straight segments 22 and 24 are joined together by a reversing bend 26. As illustrated in Figure 9, the cross-sectional area of the segments 22 and 24 are rectangular, one of the shapes shown in Figure 3. It should be noted that other cross-sections, apart those illustrated in Figure 3, can be used without departing from the spirit of the invention.

With no significant cross-sectional change occurring at the transition or near the transition 28 between the reverse bend 26 and the segments 24 or 22, the stress is transferred to the reverse bend 26 when an expansion force F tries to radially expand the stent S by moving segments 22 and 24 apart. Depending on the amount of stress induced, a bending occurs, as shown in Figure 9, where the reverse bend 26 bends out of plane so that it is no longer in alignment with the segments 22 and 24, which was its condition prior to the application of force F.

Figure 10 shows the contrast of the behavior of the reverse bend 26 when a notch 30 is placed adjacent the transition 28 between the reverse bend 26 and the segment 22 and a similar notch 32 is placed near transition 34 between the reverse bend 26 and the segment 24. What results is a reduced cross-sectional area at

transitions 28 and 34. Thus, when force F is applied to the segments 22 and 24, there is a permanent bending occurring at the zone of least cross-sectional area, *i.e.*, transitions 28 and 34, with their respective notches 30 and 32. Accordingly, the stress from radial expansion of a ring 10 as illustrated in Figure 1 is absorbed by a bending or deformation at the transitions 28 and 32, thus minimizing if not eliminating the applied stress to the reverse bend 26 after radial expansion of the stent S by expanding all of the rings 10. This type of structure illustrated in Figure 10 can be employed in the unrolled stent shown in Figures 1 and 2.

Other alternative mechanisms for reducing the stress at the reverse bend are illustrated in Figures 5–8. It should be noted that the features illustrated in Figures 5–8 are to be found in the stent shown in Figures 1 and 2; however, in order to show the overall layout of the stent S, Figures 1 and 2 are not sufficiently magnified so that these details can be seen. However, Figures 5–8 represent a greater magnification of adjacent reverse bends, such as 12 and 14.

In Figure 6, the connecting segments 36 and 38 have a smaller cross-sectional area than the cross-sectional area at the reverse bends 12 and 14, thus creating zones of transition of cross-section 40 adjacent reverse bend 14 and 42 adjacent reverse bend 12. This construction is typical for each of the rings 10 of a particular stent. It should be noted that the various features illustrated in Figures 5–8 can be used uniformly throughout the stent or mixed and matched for a desired effect.

The detail in Figure 7 illustrates a cross-sectional area transition point 44 and 46, respectively adjacent reverse bends 12 and 14. Here, there is not only a transition cross-sectional area but transverse tabs 48 are used to secure the joint between segments 50 and 52, which have a smaller cross-sectional area than the cross-sectional area of reverse bends 12 and 14.

Figure 8 illustrates the use of opposed notches 54 and 56 adjacent the entrance and exit to each reverse bend 12 and 14. Figure 5 illustrates the use of similar notches 58 and 60 at the entrance and exit of each reverse bend 12 and 14. The difference between Figure 5 and Figure 8 is that in Figure 8, the notches 54 and 56 oppose each other at the entrance and exit of each reverse bend 12 or 14, while in Figure 5 the notches can be interiorly located, as shown in Figure 5, or in the alternative, exteriorly located at the entrance and exit to each reverse bend 12 and 14. It should be noted that the changes in cross-sectional area do not need to be literally at the point of transition between the rounded portion of a reverse bend 12 or 14 and the straight segment which adjoins the reverse bends. However, the preferred location is at that transition. Locating the cross-sectional area change before entering the transition from the straight segment to the curved segment is also possible, depending on the degree of stress relief desired.

Figure 11 illustrates the stent S shown in unrolled form in Figures 1 and 2 in a perspective view after radial expansion. It should be noted that the crossties 16 retain their flexibility, even after expansion, and that the reverse bends 12 and 14 have not buckled out of the cylindrical surface defined by the expanded stent S shown in Figure 11. The buckling feature, which can occur in prior designs without the stress relief mechanism, is illustrated in Figure 9.

Figure 4 illustrates that it is within the purview of the invention to use a plurality of rings 10 connected by flexible crossties 16 without the change in cross-sectional area occurring at the reverse bends 12 and 14. While the embodiments in Figures 5-8 are preferred, it is within the purview of the invention to provide a stent with a multiplicity of rows 10 of undulating wire components which are connected by one or more crossties 16, each of which have at least one bend so that upon radial expansion into the position shown in Figures 2 and 11, the cross-

ties **16** continue to retain flexibility in at least one but preferably more directions. Thus, the individual rings **10** have longitudinal flexibility and may rotate to some degree with respect to each other, all to conform to the tortuous path in which the stent **S** may be placed. By adding the change in the cross-sectional area feature, as shown in Figures 5–8, by using one or more of those features in a single stent, a stent is produced that is flexible, yet when expanded, retains its flexibility and is not subjected to stress to a significant degree at reversing bends after complete radial expansion. By focusing the stress occurring during radial expansion to a particular point outside the reversing bend, a simple-to-make construction occurs which addresses the concerns of some of the prior art designs which have tackled this problem by using varying degrees of curvature, such as European application No. 0662307, assigned to Advanced Cardiovascular Systems. This design, with the flexible crossties **16**, represents a considerably more flexible design than rolled up coil springs such as that illustrated in U.S. Patent 4,969,458. Crossties which are essentially straight, such as those illustrated in U.S. Patent 5,421,955, do not afford the flexibility realized by the stent **S** of the present invention. It should be noted that as more bulk is presented at the transition between segments such as **22** and **24** in Figure 9, the more likely is the bending to occur when subjected to radial expansion, as illustrated schematically by force **F**. Thus, designs that use doubled up wires at the apex, such as European application No. 0421729, assigned to Medtronic, exacerbate the bending results shown in Figure 9, as well as increasing the stiffness of the stent and the force necessary for radial expansion of each of its individual rings. Additionally, by use of crossties which are coiled springs which protrude out of the cylindrical surface defined by the stent **S**, additional complications are created since the crossties will intrude into the vascular wall, creating

additional irritation to the patient or worse damage if there is penetration of the vascular wall.

Accordingly, the above-described stent S of the present invention has the advantages of flexibility in view of the unique crossties which are used. The crossties remain in the cylindrical surface defined by the shape of the stent S, even upon radial expansion. The crossties 16 retain their flexibility, even after full radial expansion occurs. By use of the cross-sectional area changes, the applied stresses from radial expansion are focused to this transition zone as opposed to other places, such as the return bends. By focusing the deformation to the transition zone, stress is minimized or reduced in the reverse bend section, such as 12 or 14, and further the tendency of the reverse bends such as 12 or 14 to protrude out of the cylindrical surface defined by the stent S is greatly reduced, if not eliminated.

The foregoing disclosure and description of the invention are illustrative and explanatory thereof, and various changes in the size, shape and materials, as well as in the details of the illustrated construction, may be made without departing from the spirit of the invention.

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CLAIMS

1. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape; and

at least one crosstie connecting adjacent rings, said crosstie disposed in general alignment with said cylindrical shape defined by said rings and having an elongated shape, with at least one bend between adjacent rings which it connects.

2. The stent of claim 1, wherein:

each said ring is made from an elongated wire-like member having an undulating pattern using reversing bends.

3. The stent of claim 2, wherein:

the cross-section of said wire-like material changes adjacent at least one of said reversing bends.

4. The stent of claim 3, wherein:

said change in cross-section is accomplished by at least one notch.

5. The stent of claim 4, wherein:

said change in cross-section is accomplished by opposed notches.

6. The stent of claim 3, wherein:

said straight section has a smaller cross-sectional area than the cross-sectional area through said reverse bend.

7. The stent of claim 6, wherein:
said straight section is joined to said reverse bend by a tab.

8. The stent of claim 3, wherein:
said wire ~~-like material-~~ member changes cross-section adjacent each said reversing bend.

9. The stent of claim 8, wherein:
said wire ~~-like material-~~ member changes cross-section on both sides of each said reversing bend.

10. The stent of claim 3, wherein:
said wire ~~-like material~~ member which comprises said rings, when said rings are expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends.

11. The stent of claim 10, wherein:
said reversing bends remain aligned to said ~~generally~~ generally cylindrical shape defined by said rings after radial expansion due to bending at said cross-sectional change locations.

12. The stent of claim 1, wherein:
said crosstie has at least two bends.

13. The stent of claim 12, wherein:
said bends define at least two slope changes in said crosstie.

14. The stent of claim 13, wherein:
each said ring is made from an elongated wire-like member having an undulating pattern using reversing bends; and
each crosstie connects a reversing bend in one of said rings to another circumferentially offset reversing bend on an adjacent ring.

15. A stent comprising:
a plurality of rings, each said ring made of a wire-like material having a plurality of reversing bends;
each adjacent pair of rings connected by at least one crosstie; and
said wire-like material changing cross-sectional area adjacent at least one of said reversing bends.

16. The stent of claim 5, wherein:
said change in cross-section is accomplished by at least one notch.

17. The stent of claim 16, wherein:
said change in cross-sectional area is accomplished by opposed notches.

18. The stent of claim 15, wherein:
said straight section has a smaller cross-sectional area than the cross-sectional area through an adjacent said reverse bend.

19. The stent of claim 18, wherein:
said straight section is joined to said reverse bend by a tab.

20. The stent of claim 15, wherein:
said wire ~~like material~~ member changes cross-section adjacent each said reversing bend.

21. The stent of claim 20, wherein:
said wire ~~like material~~ member changes cross-section on both sides of each said reversing bend.

22. The stent of claim 15, wherein:
said wire ~~like material~~ member which comprises said rings, when said rings are expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends.

23. The stent of claim 22, wherein:
said reversing bends remain aligned to said ~~generally~~ generally cylindrical shape defined by said rings after radial expansion due to bending at said cross-sectional change locations.

24. The stent of claim 23, wherein:
said crosstie has at least two bends.

25. The stent of claim 24, wherein:

said bends define at least two slope changes in said ~~crosstie~~ crossties.

26. The stent of claim 25, wherein:

each said ring is made from an elongated wire-like member having an undulating pattern using reversing bends; and

each crosstie connects a reversing bend in one of said rings to another circumferentially offset reversing bend on an adjacent ring.

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Attorney's Docket No.: WIJAY-05

Applicant: Bandula Wijay
Serial No.: Unknown
Filed: Herewith
For: Flexable Stent

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27(b)) – INDEPENDENT INVENTOR

As below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled *Flexable Stent*, described in the specification filed herewith.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

_X_ no such person, concern, or organization

___ persons, concerns or organizations listed below

Full Name NONE
Address _____

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Bandula Wijay

1-4-96.
Date

wijay\Assmnty.bj

Attorney's Docket No: WJAY-05

COMBINED DECLARATION AND POWER OF ATTORNEY

As the below named inventor, I hereby declare that this declaration is of the following type: ORIGINAL.

My residence, post office address, and citizenship are as stated below next to my name, I believe I am the original, first, and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **"Flexible Stent"**, the specification of which is attached hereto. I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application, in accordance with 37 C.F.R. § 1.56(a).

POWER OF ATTORNEY

As the named inventor, I hereby appoint the following attorneys and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Steve Rosenblatt	Reg. No. 30,799
David Mossman	Reg. No. 29,570
Richard T. Redano	Reg. No. 32,292
Paula D. Morris	Reg. No. 31,516
Daniel Venglarik	Reg. No. 39,409
Joby A. Hughes	Reg. No. 35,550

6

Direct correspondence and telephone calls to:

Steve Rosenblatt
Rosenblatt & Redano, P.C.
One Greenway Plaza, Suite 500
Houston, Texas 77046
(713) 552-9900

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME AND ADDRESS OF INVENTOR:

1-00

Name: Bandula Wijay
Residence: 1903 Carriage Creek Drive
Friendswood, Texas 77546 TX
Post Office Address: same
Citizenship: United States

1-4-96
Date

Inventor's signature

wijay\05decl.taj

PRINT OF DRAWINGS
AS ORIGINALLY FILED

08/582657

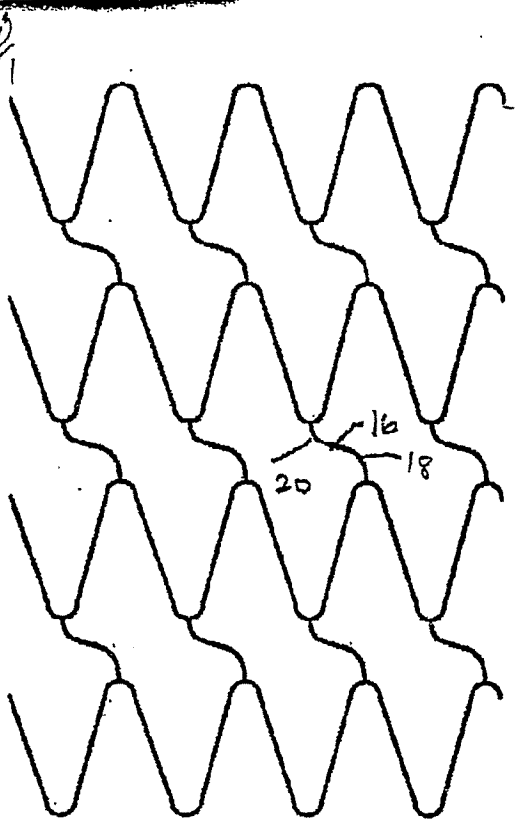


Fig 2

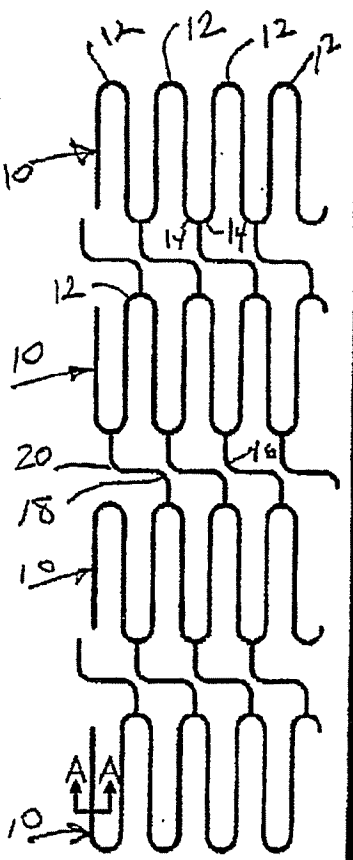


Fig 1

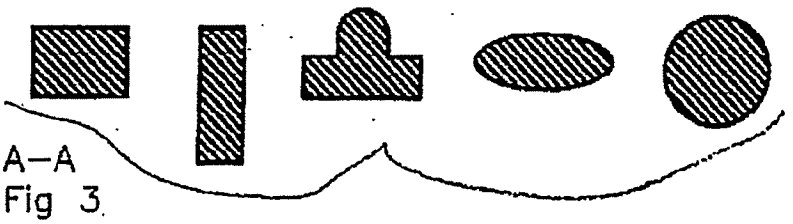
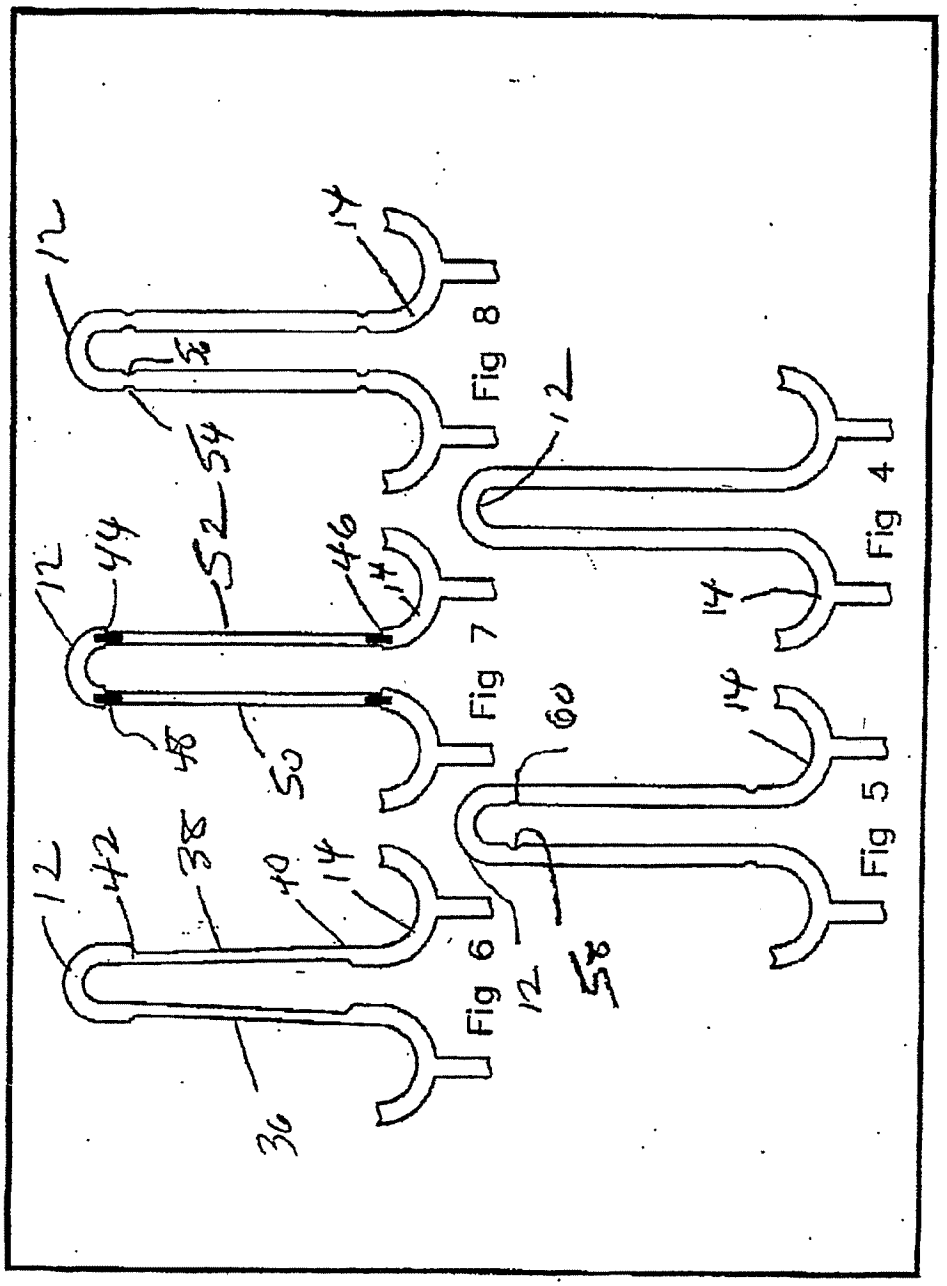


Fig 3

PRINT OF DRAWINGS
AS ORIGINALLY FILED

07582657



P.83

PRINT OF DRAWINGS
AS ORIGINALLY FILED

07/582657

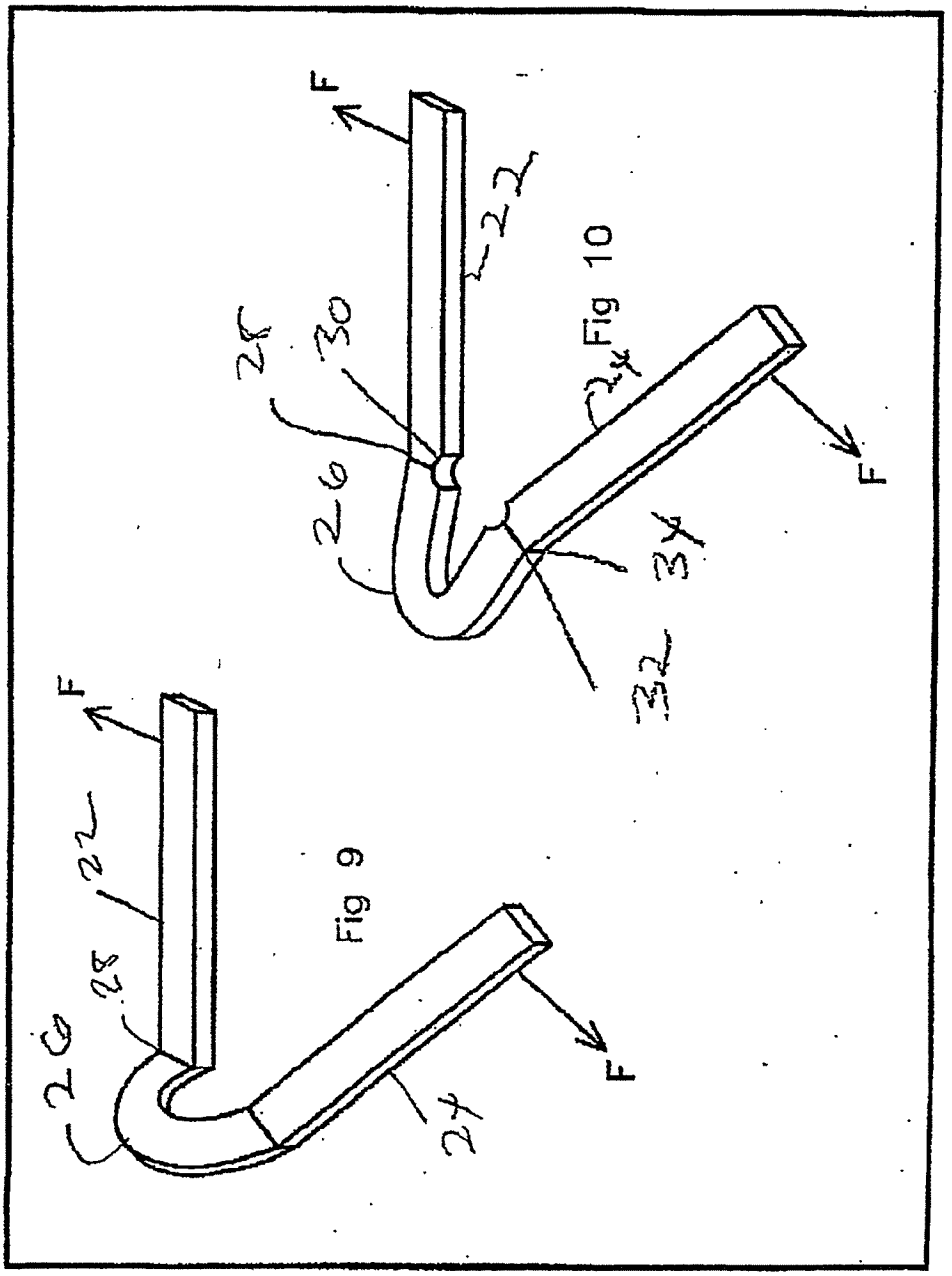


Fig 10

Fig 9

PRINT OF DRAWINGS
AS ORIGINALLY FILED

07582657

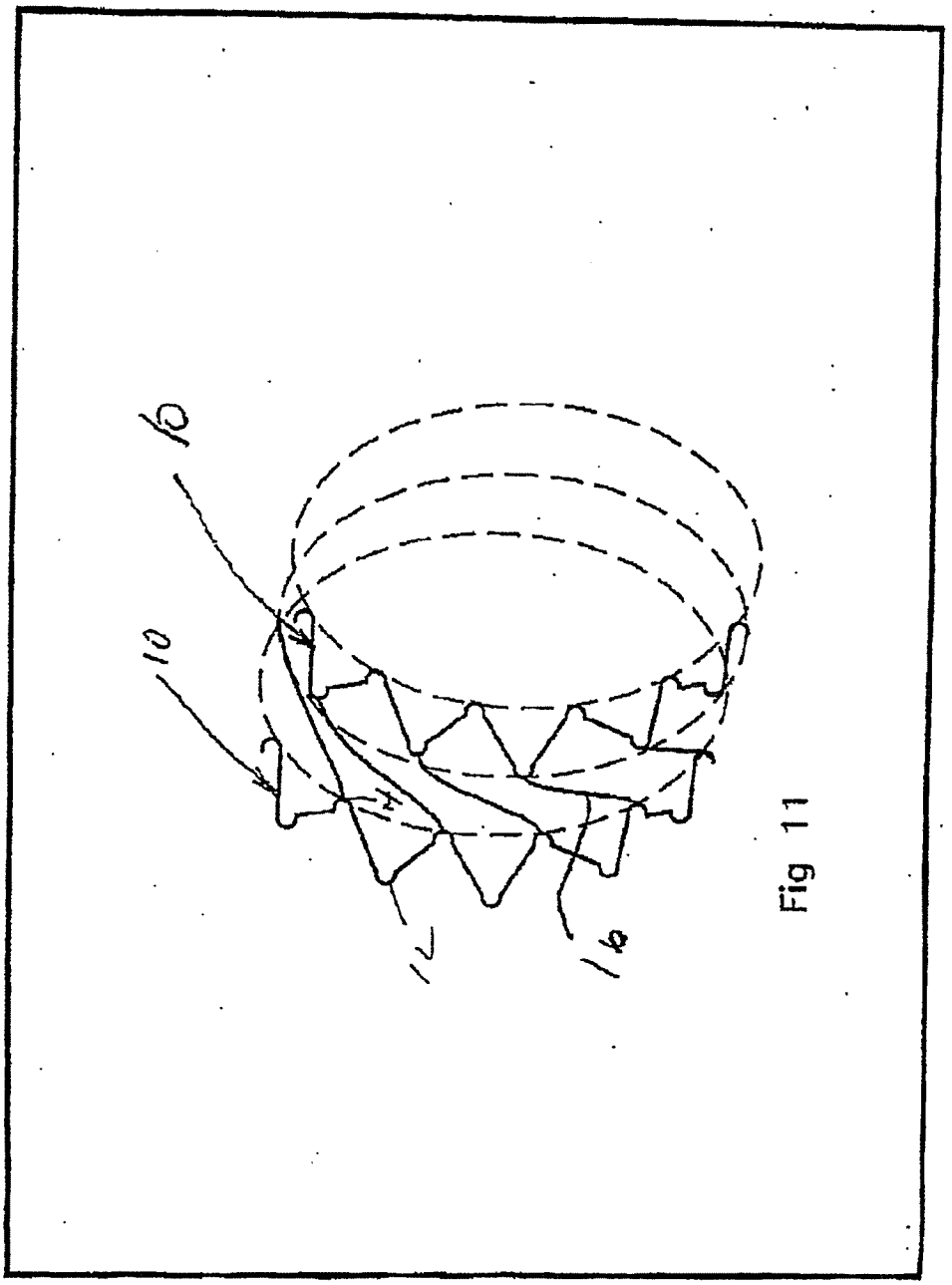


Fig 11

08/582657

5-9-96 #2 IDS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bandula Wijay	§	
		§	Group Art Unit:
Serial No:		§	
		§	Examiner:
Filed:		§	
		§	Attorney Docket: WIJAY-05
For:	Flexible Stent	§	

Commissioner of Patents & Trademarks
Washington, D. C. 20231

INFORMATION DISCLOSURE STATEMENT

In compliance with the information disclosure statement requirements of 37 C.F.R. 1.97, Applicant hereby submits the following statement which accompanies the new patent application submitted herewith.

The references set forth in form PTO-1449 are attached hereto.

U.S. Patent No. 4,580,568
U.S. Patent No. 4,820,298
U.S. Patent No. 4,886,062
U.S. Patent No. 4,969,458
U.S. Patent No. 5,133,732
U.S. Patent No. 5,139,480
U.S. Patent No. 5,195,984
U.S. Patent No. 5,213,561
U.S. Patent No. 5,222,969
U.S. Patent No. 5,222,971
U.S. Patent No. 5,234,457
U.S. Patent No. 5,258,042
U.S. Patent No. 5,266,073
U.S. Patent No. 5,282,823
U.S. Patent No. 5,287,861
U.S. Patent No. 5,292,331
U.S. Patent No. 5,304,121
U.S. Patent No. 5,306,294
U.S. Patent No. 5,314,472
U.S. Patent No. 5,334,201
U.S. Patent No. 5,336,518
U.S. Patent No. 5,342,348
U.S. Patent No. 5,344,426
U.S. Patent No. 5,360,401
U.S. Patent No. 5,368,566

U.S. Patent No. 5,370,691
U.S. Patent No. 5,383,928
U.S. Patent No. 5,389,106
U.S. Patent No. 5,391,172
U.S. Patent No. 5,397,355
U.S. Patent No. 5,403,341
U.S. Patent No. 5,421,955
U.S. Patent No. 5,423,885
U.S. Patent No. 5,433,706
U.S. Patent No. 5,437,632
U.S. Patent No. 5,439,444
U.S. Patent No. 5,439,445
U.S. Patent No. 5,443,500
EPO Application 90310775.3
EPO Application 94302929.8
EPO Application 94309839.2

AngioStent Balloon Expandable Stent System, AngioDynamics Division of E-Z-EM, Inc., Sept., 1994 (brochure)

Gianturco-Roubin Flex-Stent Coronary Stents, Cook Cardiology, 1995 (brochure)

Medtronic WIKTOR GX, Medtronic Interventional Vascular, no date (brochure)

Miscellaneous literature regarding PS stent, no date

Miscellaneous literature regarding stent, no date

Miscellaneous literature regarding Wiktor Stents, no date

Miscellaneous literature regarding Wallstent, no date

Donald S. Baim, MD, "New Stent Designs," 2 pages, dated after August, 1995

Respectfully submitted,

ROSENBLATT & REDANO, P.C.

1/4/96
Date

Steve Rosenblatt
Registration No. 30,799
One Greenway Plaza, Suite 500
Houston, TX 77046
Telephone: (713) 552-9900
Facsimile: (713) 552-0109

wjsay05ids.pto

Form PTO-1449 (Modified) List of Patents and Publications For Applicant's Information Disclosure Statement (Use several sheets if necessary)	Atty Docket No. WIJAY-04	Serial No.
	Applicant Bandula Wijay	
	Filing Date	Group

U. S. PATENT DOCUMENTS

Initials		Document Number	Date	Name	Cl	Sub	Filing Date
	AA	4,580,568	04/86	Gianturco			
	AB	4,820,298	04/89	Leveen, et al.			
	AC	4,856,062	12/89	Wiktor			
	AD	4,969,458	11/90	Wiktor			
	AE	5,133,732	07/92	Wiktor			
	AF	5,139,480	08/92	Hickle, et al.			
	AG	5,155,984	03/93	Schatz			
	AH	5,213,561	05/93	Weinstein, et al.			
	AI	5,222,969	06/93	Gillis			
	AJ	5,222,971	06/93	Willard, et al.			
	AK	5,234,457	08/93	Anderson			

FOREIGN PATENT DOCUMENTS

Initials		Document Number	Date	Country	Cl	Sub	Translation
	AL	90310775.3	10/90	EPO			
	AM	94302929.8	04/94	EPO			
	AN	94309839.2	12/94	EPO			
	AO						
	AP						

OTHER ART (Including Author, Title, Date Pertinent Pages, Etc.)

	AQ	AngioStent Balloon Expandable Stent System, AngioDynamics Division of E-Z-EM, Inc., Sept., 1994 (brochure)
	AR	Gianturco-Roubin Flex-Stent Coronary Stents, Cook Cardiology, 1995 (brochure)
	AS	Medtronic WIKTOR GX, Medtronic Interventional Vascular, no date (brochure)
	AT	Miscellaneous literature regarding PS stent, no date
	AU	

Examiner	Date Considered
J.M. Black	29 August 1996

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 (Modified) List of Patents and Publications for Applicant's Information Disclosure Statement (Use several sheets if necessary)	Atty Docket No. WJAY-04	Serial No.
	Applicant Bandula Wijay	
	Filing Date	Group

U. S. PATENT DOCUMENTS

Initials		Document Number	Date	Name	Cl	Sub	Filing Date
	AA	5,258,042	11/93	Mehta			
	AB	5,266,073	11/93	Wall			
	AC	5,282,823	02/94	Schwartz, et al.			
	AD	5,287,861	02/94	Wilk			
	AE	5,292,331	03/94	Boneau			
	AF	5,304,121	04/94	Sahatjian			
	AG	5,306,294	04/94	Winston, et al.			
	AH	5,314,472	05/94	Fontaine			
	AI	5,334,201	08/94	Cowan			
	AJ	5,336,518	08/94	Narayanan, et al.			
	AK	5,342,348	08/94	Kaplan			

FOREIGN PATENT DOCUMENTS

Initials		Document Number	Date	Country	Cl	Sub	Translation
	AL						
	AM						
	AN						
	AO						
	AP						

OTHER ART (Including Author, Title, Date Pertinent Pages, Etc.)

	AR	Miscellaneous literature regarding stent, no date
	AS	Miscellaneous literature regarding Wiktor Stents, no date
	AT	Miscellaneous literature regarding Wallstent, no date
	AU	Doanld S. Baim, MD, "New Stent Designs," 2 pages, dated after August, 1995

Examiner	Date Considered
J. M. Black	29 August 1996

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO–1449 (Modified) List of Patents and Publications For Applicant's Information Disclosure Statement (Use several sheets if necessary)	Atty Docket No. WIJAY-04	Serial No. 843,801
	Applicant Bandula Wijay	
	Filing Date	Group

U. S. PATENT DOCUMENTS

Initials		Document Number	Date	Name	Cl	Sub	Filing Date
AW2	AA	5,344,428	09/94	Lau, et al.			
AW2	AB	5,360,401	11/94	Turnland			
AW2	AC	5,368,566	11/94	Crocker			
AW2	AD	5,370,691	12/94	Samson			
AW2	AE	5,383,928	01/95	Scott, et al.			
AW2	AF	5,389,106	02/95	Tower			
AW2	AG	5,391,172	02/95	Williams, et al.			
AW2	AH	5,397,355	03/95	Marin, et al.			
AW2	AI	5,421,955	06/95	Lau, et al.			
AW2	AJ	5,423,885	06/95	Williams			
AW2	AK	5,433,706	07/95	Abluso			

FOREIGN PATENT DOCUMENTS

Initials	Document Number	Date	Country	Cl	Sub	Translation
AL						
AM						
AN						
AO						
AP						

OTHER ART (Including Author, Title, Date Pertinent Pages, Etc.)

AR	
AS	
AT	
AU	

Examiner	Date Considered
J. M. Black	29 August 1996

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 (Modified) List of Patents and Publications For Applicant's Information Disclosure Statement (Use several sheets if necessary)	Atty Docket No. WIJAY-04	Serial No. 08/383,601
	Applicant Bandula Wijay	
	Filing Date	Group

U. S. PATENT DOCUMENTS

Initials		Document Number	Date	Name	Cl	Sub	Filing Date
	AA	5,457,632	08/95	Engelson			
	AB	5,439,444	08/95	Anderson, et al.			
	AC	5,439,445	08/95	Kontos			
	AD	5,443,500	08/95	Sigwart			
	AE	5,403,341	04/95	Solar			
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

Initials		Document Number	Date	Country	Cl	Sub	Translation
	AL						
	AM						
	AN						
	AO						
	AP						

OTHER ART (Including Author, Title, Date Pertinent Pages, Etc.)

	AR	
	AS	
	AT	
	AU	

Examiner	Date Considered
J. M. Olaiz	29 August 1996

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bandula Wijay	Group Art Unit:	
Serial No:	08/582,657	Examiner:	
Filed:	January 4, 1996	Attorney-Docket:	WIJAY-05
For:	Flexible Stent		

TRANSMITTAL AND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents & Trademarks
Washington, D. C. 20231

The supplemental information disclosure statement submitted herewith is being filed within three months of the filing date of the application. 37 C.F.R. 1.97(b).

In compliance with the information disclosure statement requirements of 37 C.F.R. 1.97, Applicant hereby submits **U.S. Patent No. 4,776,337,** which in connection with the above-identified patent application. The reference set forth in form PTO-1449 is attached hereto.

Respectfully submitted,

February 7, 1996

Steve Rosenblatt
Registration No. 30,799
ROSENBLATT & REDANO, P.C.
One Greenway Plaza, Suite 500
Houston, TX 77046
Telephone: (713) 552-9900
Facsimile: (713) 552-0109

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

I hereby certify that this paper, along with any referred to as being attached or enclosed, is being forwarded to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, via the United States Postal Service, first class mail, postage prepaid, on Feburary 7, 1996.

wijay05ids.197

eet 1 of 1

FACSIMILE OF FORM PTO-1449 (REV. 6-89) U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office	ATTORNEY'S DOCKET NUMBER	SERIAL NUMBER
INFORMATION DISCLOSURE CITATION (Use Several Sheets if Necessary) RECEIVED MAY 2 9 1996	WIJAY-05	08/582,657
	APPLICANT: Bendula Wijay	
	FILING DATE: January 4, 1996	GROUP ART UNIT

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JMC	4,776,337	10/88	Palmaz			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER: J.M. Clark	DATE CONSIDERED: 29 August 1996

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the patent owner.

3360 3308

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#4

Applicant:	Vandula Wijay	§	
		§	Group Art Unit: ~~3304~~
Serial No:	08/582,657	§	
		§	Examiner:
Filed:	January 4, 1996	§	
		§	Attorney Docket:- WIJAY-05
For:	Flexible Stent	§	

TRANSMITTAL AND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents & Trademarks
Washington, D. C. 20231

The supplemental information disclosure statement submitted herewith is being filed before the mailing date of the first Office action for this application. 37 C.F.R. 1.97(b).

In compliance with the information disclosure statement requirements of 37 C.F.R. 1.97, Applicant hereby submits this statement in connection with the above-identified patent application. The references set forth in form PTO-1449 is attached hereto.

Respectfully submitted,

4-25-96
Date

Steve Rosenblatt
Registration No. 30,799
ROSENBLATT & REDANO, P.C.
One Greenway Plaza, Suite 500
Houston, TX 77046
Telephone: (713) 552-9900
Facsimile: (713) 552-0109

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

I hereby certify that this paper, along with any referred to as being attached or enclosed, is being forwarded to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, via the United States Postal Service, first class mail, postage prepaid, on the 25 day of April, 1996.

wijay\ids\05ids02.197

FACSIMILE OF FORM PTO-1449 (REV. 6-89) U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office	ATTORNEY'S DOCKET NUMBER	SERIAL NUMBER
INFORMATION DISCLOSURE CITATION	WIJAY-05	08/582,657
(Use Several Sheets if Necessary)	APPLICANT: Bandula Wijay	
	FILING DATE: January 4, 1996	GROUP ART UNIT: 3301

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AMS	Re. 34,037	05/92	Innus, et al.			
	4,503,569	03/85	Dotter			
	4,732,152	03/88	Wallsten, et al.			
	4,740,207	04/88	Kreamer			
AMS	4,795,458	01/89	Regan			
	4,913,141	04/90	Hillstead			
	4,950,227	08/90	Savin, et al.			
AMS	4,964,853	10/90	Sugiyama, et al.			
	4,990,151	02/91	Wallsten			
	5,100,429	03/92	Sinofsky, et al.			
AMS	5,108,416	04/92	Ryan, et al.			
AMS	5,135,536	08/92	Hillstead			
AMS	5,158,548	10/92	Lau, et al.			
AMS	5,160,341	11/92	Brenneman, et al.			
AMS	5,163,951	11/92	Pinchuk, et al.			
AMS	5,163,952	11/92	Froix			
AMS	5,163,958	11/92	Pinchuk			
	5,197,978	03/93	Hess			
	5,282,824	02/94	Gianturco			
AMS	5,480,423	01/96	Ravenscroft, et al.			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER	DATE CONSIDERED
J. M. Buck	29 August 1996

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the patent owner.

08/582,657

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/582,657	01/04/96	WIJAY B	WIJAY-05

F3M1/0905

BLACK, J EXAMINER

STEVE ROSENBLATT
ROSENBLATT & REDANO
ONE GREENWAY PLAZA
SUITE 500
HOUSTON TX 77046

ART UNIT	PAPER NUMBER
3308	5

DATE MAILED: 09/05/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1-26 are pending in the application.
   Of the above, claims 7 and 19 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1-3, 6, 8-16, 18 and 20-26 are rejected.
5. ☑ Claims 4, 5, and 17 are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☑ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

Election/Restriction

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Figures 4, 5, 6, 7 and 8.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 12, 13 and 14 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

2. During a telephone conversation with Mr. Steve Rosenblatt on 21 August 1996 a provisional election was made with traverse

to prosecute the invention of Figure 6, claims 1-6, 8-18 and 20-26. Affirmation of this election must be made by applicant in responding to this Office action. Claims 7 and 19 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

4. Claims 3, 6, 8-11, 16, 18 and 23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following lack antecedent basis:

Claim 3, line 2, "the cross-section" and "said wire-like material";

Claim 6, line 2, "said straight section";

Claim 8, line 2, "said wire-like material";

Claim 9, line 2, "said wire-like material";

Claim 10, line 2, "said wire-like material";

Claim 11, line 2, "said generally cylindrical shape";

Claim 18, line 2, "said straight section";

Claim 23, line 2, "said generally cylindrical shape".

With respect to claim 16, it is unclear how claim 16 can contain a single notch when it depends from claim 5, and claim 5 contains two notches.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1, 2 and 12-14 are rejected under 35 U.S.C. § 102(e) as being anticipated by Pinchasik et al.

Pinchasik et al. show the invention as claimed where elements 112 are crossties and elements 108 are rings as best seen in Fig. 2C.

7. Claims 1-3, 6, 8-15, 18 and 20-26 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cardon et al.

With respect to claims 1, 2, 12, 13, 24 and 25, Cardon et al. show the invention substantially as claimed where elements 7 are crossties and the rings are located in regions 1 and 1' as best seen in Figs. 1 and 2.

With respect to claims 3, 8, 9, 15, 20 and 21, Cardon et al. show the change in cross-section in the ring segments as represented by e, e', and e" as best seen in Fig. 3.

With respect to claim 6 and 18, it appears that e is less than e' or e" as best seen in Fig. 3.

With respect to claims 10 and 22, the ring elements bend when the stent expands as best seen in Fig. 4.

With respect to claims 11 and 23, the rings remain in a cylindrical shape when the stent expands as best seen in Fig. 2.

With respect to claims 14 and 26, it appears that each crosstie connects circumferentially offset rings as best seen in Fig. 2.

Allowable Subject Matter

8. Claims 4, 5 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claim 16 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112 and to include all of the limitations of the base claim and any intervening claims.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John M. Black whose telephone number is (703) 305-7341. If unavailable, you may contact John G. Weiss, Supervisory Patent Examiner, at (703) 308-2702. Any communications may be faxed to Group 3300 at (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist whose telephone number is (703) 308-0858.

JMB
September 2, 1996

JOHN G. WEISS
SUPERVISORY PATENT EXAMINER
GROUP 3300

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP–APART AND DISCARD CARBON

FORM PTO-892 (REV. 2-92)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
NOTICE OF REFERENCES CITED		08/582,657	3308	5
		APPLICANT(S) BANDULA WIJAY		

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	5383892	1/1995	CARDON et al.	606	198	
	B	5449373	9/1995	PINCHASIK et al.	606	198	
	C						
	D						
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L	9113820	11/1991	FRANCE	CARDON	A61F	2/04		
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

R	
S	
T	
U	

EXAMINER	DATE
J. M. BLACK	2 SEPT. 1996

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

Form PTO 948 (Rev. 10-93) U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No. 58257

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

PTO Draftpersons review all originally filed drawings regardless of whether they are designated as formal or informal. Additionally, patent Examiners will review the drawings for compliance with the regulations. Direct telephone inquiries concerning this review to the Drawing Review Branch, 703-305-8404.

The drawings filed (insert date)_____, are
A.___ not objected to by the Draftsperson under 37 CFR 1.84 or 1.152.
B. X objected to by the Draftsperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawings must be submitted according to the instructions on the back of this Notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color.
   ___ Not black solid lines. Fig(s)_____
   ___ Color drawings are not acceptable until petition is granted.

2. PHOTOGRAPHS. 37 CFR 1.84(b)
   ___ Photographs are not acceptable until petition is granted.

3. GRAPHIC FORMS. 37 CFR 1.84 (d)
   ___ Chemical or mathematical formula not labeled as separate figure. Fig(s)_____
   ___ Group of waveforms not presented as a single figure, using common vertical axis with time extending along horizontal axis. Fig(s)_____
   ___ Individual waveform not identified with a separate letter designation adjacent to the vertical axis. Fig(s)_____

4. TYPE OF PAPER. 37 CFR 1.84(e)
   ___ Paper not flexible, strong, white, smooth, nonshiny, and durable. Sheet(s)_____
   ___ Erasures, alterations, overwritings, interlineations, cracks, creases, and folds not allowed. Sheet(s)_____

5. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable paper sizes:
   21.6 cm. by 35.6 cm. (8 1/2 by 14 inches)
   21.6 cm. by 33.1 cm. (8 1/2 by 13 inches)
   21.6 cm. by 27.9 cm. (8 1/2 by 11 inches)
   21.0 cm. by 29.7 cm. (DIN size A4)
   ___ All drawing sheets not the same size. Sheet(s)_____
   ___ Drawing sheet not an acceptable size. Sheet(s)_____

6. MARGINS. 37 CFR 1.84(g): Acceptable margins:

Paper size	21.6 cm. X 35.6 cm. (8 1/2 X 14 inches)	21.6 cm X 33.1 cm. (8 1/2 X 13 inches)	21 cm. X 27.9 cm. (8 1/2 X 11 inches)	21 cm. X 29.7 cm. (DIN Size A4)
T	5.1 cm. (2")	2.5 cm. (1")	2.5 cm. (1")	2.5cm.
L	.64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	2.5 cm.
R	.64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	1.5 cm.
B	.64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	1.0 cm.

   Margins do not conform to chart above.
   Sheet(s)_____
   ___Top (T) ___ Left (L) ___Right (R) ___Bottom (B)

7. VIEWS, 37 CFR 1.84(h)
   REMINDER: Specification may require revision to correspond to drawing changes.
   ___ All views not grouped together. Fig(s)_____
   ___ Views connected by projection lines. Fig(s)_____
   ___ Views contain center lines. Fig(s)_____

Partial views. 37 CFR 1.84(h)(2)
   ___ Separate sheets not linked edge to edge. Fig(s)_____
   ___ View and enlarged view not labeled separately. Fig(s)_____
   ___ Long view relationship between different parts not clear and unambiguous. 37 CFR 1.84(h)(2)(ii) Fig(s)_____

Sectional views. 37 CFR 1.84(h)(3)
   ___ Hatching not indicated for sectional portions of an object. Fig(s)_____
   ___ Hatching of regularly spaced oblique parallel lines not spaced sufficiently. Fig(s)_____
   ___ Hatching not at substantial angle to surrounding axes or principal lines. Fig(s)_____
   ___ Cross section not drawn same as view with parts in cross section with regularly spaced parallel oblique strokes. Fig(s)_____
   ___ Hatching of juxtaposed different elements not angled in a different way. Fig(s)_____

Alternate position. 37 CFR 1.84(h)(4)
   ___ A separate view required for a moved position. Fig(s)_____

Modified forms. 37 CFR 1.84(h)(5)
   ___ Modified forms of construction must be shown in separate views. Fig(s)_____

8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   ___ View placed upon another view or within outline of another. Fig(s)_____
   ___ Words do not appear in a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s)_____

9. SCALE. 37 CFR 1.84(k)
   ___ Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s)_____
   ___ Indication such as "actual size" or "scale 1/2" not permitted. Fig(s)_____
   ___ Elements of same view not in proportion to each other. Fig(s)_____

10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)
   ___ Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (except for color drawings). Fig(s)_____

11. SHADING. 37 CFR 1.84(m)
   ___ Shading used for other than shape of spherical, cylindrical, and conical elements of an object, or for flat parts. Fig(s)_____
   ___ Solid black shading areas not permitted. Fig(s)_____

12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
   ___ Numbers and reference characters not plain and legible. 37 CFR 1.84(p)(1) Fig(s)_____
   ___ Numbers and reference characters used in conjuction with brackets, inverted commas, or enclosed within outlines. 37 CFR 1.84(p)(1) Fig(s)_____
   ___ Numbers and reference characters not oriented in same direction as the view. 37 CFR 1.84(p)(1) Fig(s)_____
   ___ English alphabet not used. 37 CFR 1.84(p)(2) Fig(s)_____
   ___ Numbers, letters, and reference characters do not measure at least .32 cm. (1/8 inch) in height. 37 CFR(p)(3) Fig(s)_____

13. LEAD LINES. 37 CFR 1.84(q)
   ___ Lead lines cross each other. Fig(s)_____
   ___ Lead lines missing. Fig(s)_____
   ___ Lead lines not as short as possible. Fig(s)_____

14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
   ___ Number appears in top margin. Fig(s)_____
   ___ Number not larger than reference characters. Fig(s)_____
   ___ Sheets not numbered consecutively, and in Arabic numerals, beginning with number 1. Sheet(s)_____

15. NUMBER OF VIEWS. 37 CFR 1.84(u)
   ___ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s)_____
   ___ View numbers not preceded by the abbreviation Fig. Fig(s)_____
   ___ Single view contains a view number and the abbreviation Fig.
   ___ Numbers not larger than reference characters. Fig(s)_____

16. CORRECTIONS. 37 CFR 1.84(w) --
   ___ Corrections not durable and permanent. Fig(s)_____

17. DESIGN DRAWING. 37 CFR 1.152
   ___ Surface shading shown not appropriate. Fig(s)_____
   ___ Solid black shading not used for color contrast. Fig(s)_____

Remove Border Lines

ATTACHMENT TO PAPER NO. 15 REVIEWER _____ DATE 3/25/96

PTO Copy

BSC-J007961

BSC-C 017095

40/2-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant: Bhargav Wijay	§	Examiner: J. Black
Filed: January 4, 1996	§	Art Unit: 3308
Serial No. 08/582,657	§	
For: Flexible Stent	§	Docket No.: WIJAY-05

RESPONSE TO OFFICE ACTION

Assistant Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

Responsive to the Office Action mailed September 5, 1996, Applicant submits the following amendment.

IN THE SPECIFICATION

On page 8, line 16, after "double bend" please insert – spaced apart from connecting ends of crossties 16 –.

IN THE CLAIMS

Please amend the claims as follows:

1. (Amended) A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape each of said plurality of rings comprises a singular elongated wire-like member having an undulating pattern using reversing bends; and

at least one crosstie connecting adjacent rings, said crosstie disposed in general alignment with said cylindrical shape defined by said rings and having an elongated shape, with at least one bend between adjacent rings which it connects.

Please cancel claim 2 without prejudice.

3. (Amended) The stent of claim [2] 1, wherein:

[the cross-section of] said wire-like [material] member has a cross-section which changes [adjacent] between at least [one] two of said reversing bends.

Please cancel claim 4 in favor of claim 27.

In claim 5, line 1, remove "4" and insert therefor — 27 —.

6. (Amended) The stent of claim 3, wherein:

said wire-like member has straight sections between said reversing bends;

said straight [section has] sections have a smaller cross-sectional area than the cross-sectional area through said [reverse bend] reversing bends.

In claim 8, line 2, remove "material" and insert therefor — member —.

In claim 9, line 2, remove "material" and insert therefor — member —.

In claim 10, line 2, remove "material" and insert therefor — member —.

In claim 11, line 2, after "remain" insert — generally — and after "aligned to said" delete "generally".

12. (Amended) The stent of claim 1, [wherein] further comprising:

[said crosstie has] a plurality of non-overlapping crossties each having at least two bends.

In claim 13, line 2, please delete "crosstie" and insert therefor — crossties —.

14. (Amended) The stent of claim 13, wherein:

[each said ring is made from an elongated wire-like member having an undulating pattern using reversing bends; and]

each crosstie connects a reversing bend in one of said rings to [another] the next adjacent circumferentially offset reversing bend on an adjacent ring.

15. (Amended) A stent, comprising:

a plurality of rings, each said ring [made of] comprises a singular wire-like material having a plurality of reversing bends, said wire-like material comprising at least one straight section between said reversing bends;

each adjacent pair of rings connected by at least one crosstie; and

said wire-like material changing cross-sectional area in said straight section adjacent at least one of said reversing bends.

Please cancel claim 16 in favor of claim 28.

In claim 17, line 1, remove "16" and insert therefor — 28 —.

In claim 18, line 3, after "sectional area through" insert — an adjacent —.

In claim 23, line 2, after "reversing bends remain" insert — generally — and after "aligned to said" remove "generally".

24. (Amended) A stent of claim [23] 15, wherein:

[said crosstie has] a plurality of non-overlapping crossties each having at least two bends.

In claim 25, line 2, please delete "crosstie" and insert therefor — crossties —.

26. (Amended) The stent of claim 25, wherein:

[each said ring is made from an elongated wire-like member having an undulating pattern using reversing bends; and]

each crosstie connects a reversing bend in one of said rings to [another] the next adjacent circumferentially offset reversing bend on an adjacent ring.

Please add new claims 27, 28 and 29.

27. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape;

at least one crosstie connecting adjacent rings, said crosstie disposed in general alignment with said cylindrical shape defined by said rings and having an elongated shape, with at least one bend between adjacent rings which it connects;

each said ring is made from an elongated wire-like member having an undulating pattern using reversing bends;

said wire-like member having a cross-section which changes adjacent at least one of said reversing bends; and

said change in cross-section is accomplished by at least one notch.

28. A stent, comprising:

a plurality of rings, each said ring made of a wire-like material having a plurality of reversing bends;

each adjacent pair of rings connected by at least one crosstie; and

said wire-like material changing cross-sectional area adjacent at least one of said reversing bends; and

said change in cross-section is accomplished by at least one notch.

The stent of claim 1, wherein:

said at least one crosstie comprises at least two reversing bends located remotely from the ~~end connections~~ said end of said crosstie.

REMARKS

Applicant has carefully reviewed the Office Action mailed September 5, 1996. In response to paragraphs 1 and 2, Applicant affirms the election to the embodiment of Figure 6 which has resulted in current prosecution of claims 1–6, 8–18 and 20–26.

With regard to paragraph 8 of the Office Action, Applicant notes the allowability of claims 4, 5 and 17. Claim 4 has been rewritten in independent form as claim 27, further incorporating the corrections to claim 3 responsive to the § 112 rejection of claim 3 mentioned in paragraph 4 of the Office Action. Accordingly, claims 27 and 5 are now in condition for allowance.

The Examiner has raised a § 112 issue with regard to claim 16. The Examiner's point is well taken and the lack of clarity in claim 16 arises from a typographical error as to the dependency of claim 16. It was intended for claim 16 to depend on claim 15. On the assumption that claim 16 corrected to reflect its dependency on claim 15 is now in allowable condition, claim 28 is presented as a combination of original claims 15 and 16 and the dependency of claim 17 has been changed to claim 28 thereby putting claims 16 and 17 in condition for allowance. The Office Action is understood to state that the notch feature as a way of changing the cross-section is not found in the cited art of record and, therefore, it is believed that claim 28 is in allowable condition. The other

claims referred to in paragraph 4 have been amended to address the remaining § 112 issues to provide the necessary antecedent for the phrases or to revise the phrases so that they accurately reflect their antecedents.

The substantive anticipation rejections of claim 1 are Pinchasik '373 and Cardon '892. Pinchasik illustrates the use of rings made of cutouts in a cylindrical shape as shown in Figures 2b (relaxed) and 2c (expanded). These rings 102 are described as substantially rigid (column 3, line 26). They are further described at column 3 as being a fine diamond mesh of interconnected diamond shaped cells.

Cardon '892 employs rings 1 and 1' which are of a rigid construction comprising of slots cut out of tubes as described in column 4, lines 3–5. The structure of the axially rigid cylindrical part is also referred to in column 3, lines 19–23. These rings are similar to Pinchasik's. Figure 1 shows the condition upon insertion while Figure 2 shows the condition of the rigid rings after expansion.

It is apparent that the Examiner has taken a very broad view of the disclosure of these two references. Claim 1, as amended, indicates that there are a plurality of rings with at least one crosstie connecting adjacent rings wherein each ring of said plurality of rings comprises a singular wire-like member having an undulating pattern using reversing bends. This clarification in the language was intended to indicate that mesh type rings, as shown in the two cited references, made of a plurality of cutouts in tubes which are intended by design and express disclosure in these references to be rigid are not within the purview of the invention as claimed in claim 1. Claim 1 is directed at a stent having rings which have the appearance of a singular wire-like member bent in an undulating pattern using reverse bends. This structure is readily disclosed in Figures 1, 2 and 11 of the application. While such a structure can be created from etching a cylinder, the etching pattern is different than that used

in the cited references and results in singular undulating wire-like rings with reversing bends as opposed to a cellular type structure of the two cited references. It is respectfully submitted that the structure claimed in claim 1 is not only literally different but unobviously different than either of these two references which teach the use of etching a tube to create rigid rings. The design of claim 1 is more flexible over its length. Claim 1 is respectfully submitted to be allowable condition at this time.

Claim 3, now depending on claim 1, indicates that the wire-like member has a cross-section which changes between two reversing bends. Only the Cardon reference is applied to claim 3, where the Examiner makes reference to Figure 3. To the extend that Figure 3 has reversing bends as referred to by the Examiner by letters e, e' and e'', it can readily be seen that component "e" comprises the area between reversing bends and it has no change in cross-section at all. Accordingly, with the clarification of claim 3 that the wire-like member has a cross-sectional change between two reversing bends, it can readily be seen that Figure 3 of the Cardon reference teaches no such structure and, in fact, teaches away from the claimed structure by indicating a uniform dimension e along the straight segments between any bends.

For reasons given with respect to claim 3, those claims which depend on claim 3 are now also submitted to be in allowable condition.

Claim 11 is rejected in view of Cardon as being anticipated. Claim 11 indicates that the reversing bends remain aligned to the cylindrical shape defined by the rings after radial expansion due to bending at said cross-sectional change locations. The Cardon reference specifically teaches away from claim 11 in column 2, lines 60-68, where it is taught that the ends curl up during radial expansion and, by deforming outwardly, the ends sink slightly into the wall of the body where the

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stent is implanted; hence, improving the anchoring. This language in Cardon is to be compared with claim 11 and the conclusion which should be drawn is that Cardon teaches away from claim 11.

Both Pinchasik and Cardon are used to reject claim 12. Claim 12 has been further amended to indicate that the crossties are not overlapping. This can be seen in Figure 2 of the application where there is no axial overlap between two given rings of the crossties. This is to be contrasted with Pinchasik, Figure 2b or 2c, which indicates long crossties which overlap each other axially. Pinchasik's Figure 3c shows that each crosstie overlaps itself axially. The Cardon reference uses a mesh as its crosstie assembly and, therefore, by definition has overlapping crossties in two directions, axially and circumferentially. Accordingly, claim 12 is believed to be in condition for allowance.

For reasons given with regard to claim 12, claims 13 and 14 are also believed to be allowable condition. Claim 14 indicates that each crosstie connects a reversing bend on one of said rings to the next adjacent circumferentially offset reversing bend in an adjacent ring. Again, this structure is not revealed in Pinchasik and Cardon, by use of a mesh, does not begin to have such a structure.

Claim 15 has been rejected as being anticipated by Cardon. For the reasons given with regard to claim 3, it is respectfully submitted that claim 15 which has similar language is also in allowable condition being unobviously different than Cardon. For the reasons previously discussed, the remaining dependent claims from claim 15 are now also believed to be in allowable condition and such action is requested.

Claim 29 is new and is directed to the feature of the bends being located on the crosstie away from its end points. This feature is shown in Figure 1. The specification is amended to conform it to this feature as shown in Figure 1.

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For the reasons previously given with respect to claims 12 –14, it is respectfully submitted that claims 24–26 are now also in allowable condition.

Respectfully submitted,

Steve Rosenblatt
Registration No. 30,799
ROSENBLATT & REDANO, P.C.
One Greenway Plaza, Suite 500
Houston, Texas 77046
Telephone: (713) 552–9900
Facsimile: (713) 552–0109

Date: December 5, 1996

CERTIFICATE UNDER 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this 5th day of December, 1996.

Steve Rosenblatt

WIIAY\05 AMENDMENT\lee

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant:
Bandula Wijay

Filed: January 4, 1996

Serial No. 08/582,657

For: Flexible Stent

§ Examiner: J. Black

§ Art Unit: 3308

§ Docket No.: WIJAY-05

Assistant Commissioner of Patents
Washington, D.C. 20231

RESPONSE TRANSMITTAL

1. Transmitted herewith is the Response to First Office Action dated September 5, 1996, for this application.

2. Applicant is a small entity. A Verified Statement Claiming Small Entity Status was filed on January 4, 1996.

3. The fee for claims has been calculated as shown below:

	NUMBER OF CLAIMS AFTER AMENDMENT		PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE		ADDITIONAL FEE
TOTAL CLAIMS	26	-	26	=	0	X	$11	=	0
INDEPENDENT CLAIMS	4	-	3	=	1	X	$40	=	$40.00
[illegible]	[illegible]					+	$125	=	0
TOTAL FILING FEE	[illegible]								$40.00

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4. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 18-2020.

Respectfully submitted,

ROSENBLATT & REDANO, P.C.

December 5, 1996

Steve Rosenblatt
Registration No. 30,799
One Greenway Plaza, Suite 500
Houston, TX 77046
Telephone: (713) 552-9900
Facsimile: (713) 552-0109

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

I hereby certify that this paper, along with any referred to as being attached or enclosed, is being forwarded to the Assistant Commissioner of Patents, Washington, D.C. 20231, via the United States Postal Service, first class mail, postage prepaid, on this 5th day of December, 1996.

Steve Rosenblatt

WIJAY\05 AMENDMENT TRANSMITTAL\lee

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor/Applicant:
Bandula Wijay

Filed: January 4, 1996

Serial No. 08/582,657

For: Flexible Stent
Assistant Commissioner of Patents
Washington, D.C. 20231

§
§ Examiner: J. Black
§
§ Art Unit: 3308
§
§
§
§ Docket No.: WIJAY-05

RESPONSE TRANSMITTAL

1. Transmitted herewith is the Response to First Office Action dated September 5, 1996, for this application.

2. Applicant is a small entity. A Verified Statement Claiming Small Entity Status was filed on January 4, 1996.

3. The fee for claims has been calculated as shown below:

	NUMBER OF CLAIMS AFTER AMENDMENT		PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE		ADDITIONAL FEE
TOTAL CLAIMS	25	-	26	=	0	X	$11	=	0
INDEPENDENT CLAIMS	4	-	3	=	1	X	$40	=	$40.00
MULTIPLE DEPENDENT CLAIM (IF ANY)						+	$125	=	0
TOTAL FILING FEE									$40.00

A

4. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 18-2020.

Respectfully submitted,

ROSENBLATT & REDANO, P.C.

December 5, 1996

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

I hereby certify that this paper, along with any referred to as being attached or enclosed, is being forwarded to the Assistant Commissioner of Patents, Washington, D.C. 20231, via the United States Postal Service, first class mail, postage prepaid, on this 5th day of December, 1996.

Steve Rosenblatt

WUAY\05 AMENDMENT TRANSMITTAL\lee

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40-202
1-203
3308

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant: [illegible] Wijay	§	Examiner: J. Black
Filed: January 4, 1996	§	Art Unit: 3308
Serial No. 08/582,657	§	
For: Flexible Stent	§	Docket No.: WIJAY-05

OK
1-28-97
#7/Suppl
B

SUPPLEMENTAL AMENDMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

Responsive to the Office Action mailed September 5, 1996, Applicant submits the following supplemental amendment.

IN THE CLAIMS

Please add the following new claims:

B1

30. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape having a longitudinal axis;

at least one crosstie connecting adjacent rings, said crosstie disposed in general alignment with said cylindrical shape defined by said rings and having an elongated shape;

said at least one crosstie comprises at least two reversing bends located remotely from the end connections of said crosstie; and

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said bends define a turn of no less than about 90°.

31. The stent of claim 30, wherein:

said crosstie having a first end offset circumferentially from a second end.

32. The stent of claim 30, wherein:

said first and second ends up to said bends of said crosstie are in substantial longitudinal alignment with the longitudinal axis of said cylindrical shape.

REMARKS

Claims 30–32 are newly added. Claims 30–32 are distinguishable over Pinchasik in that Pinchasik employs crossties 112 which bend at the apex of the diamond mesh ring 108. In essence, the Pinchasik crossties are bent at each end point in the manner in which they are attached to the mesh ring 108 (Figure 2). In Figure 3, there are two acute reverse bends on Pinchasik's crossties. Either design is less flexible and the Figure 3 design of Pinchasik has the added disadvantage that the crossties can twist on expansion taking one of the two acute bends out away from the cylindrical profile where such acute bend can cut into the vessel wall.

Pinchasik's crossties do not have at least two bends between adjacent rings wherein the bends define a turn of no less than about 90 degrees. Claim 31 adds the feature of a circumferential offset between one end and a second end on a crosstie. Claim 32 depends on claim 30 and indicates that the crossties extend longitudinally substantially in alignment

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with the longitudinal axis of the cylindrical shape before the reverse bends are reached from either end. Allowance of these claims is also respectfully requested over the art of record.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this 18th day of December, 1996.

Lee Brevard

Lee Brevard

WIAY\05 SUPPLEMENTAL AMENDMENT\lee

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